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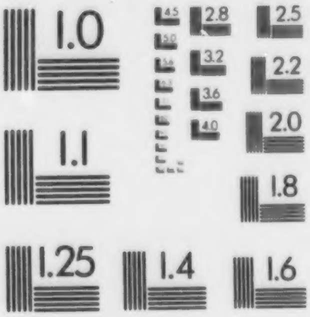

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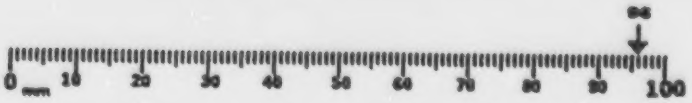

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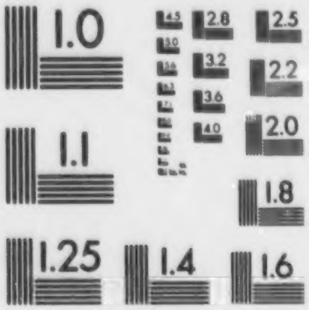

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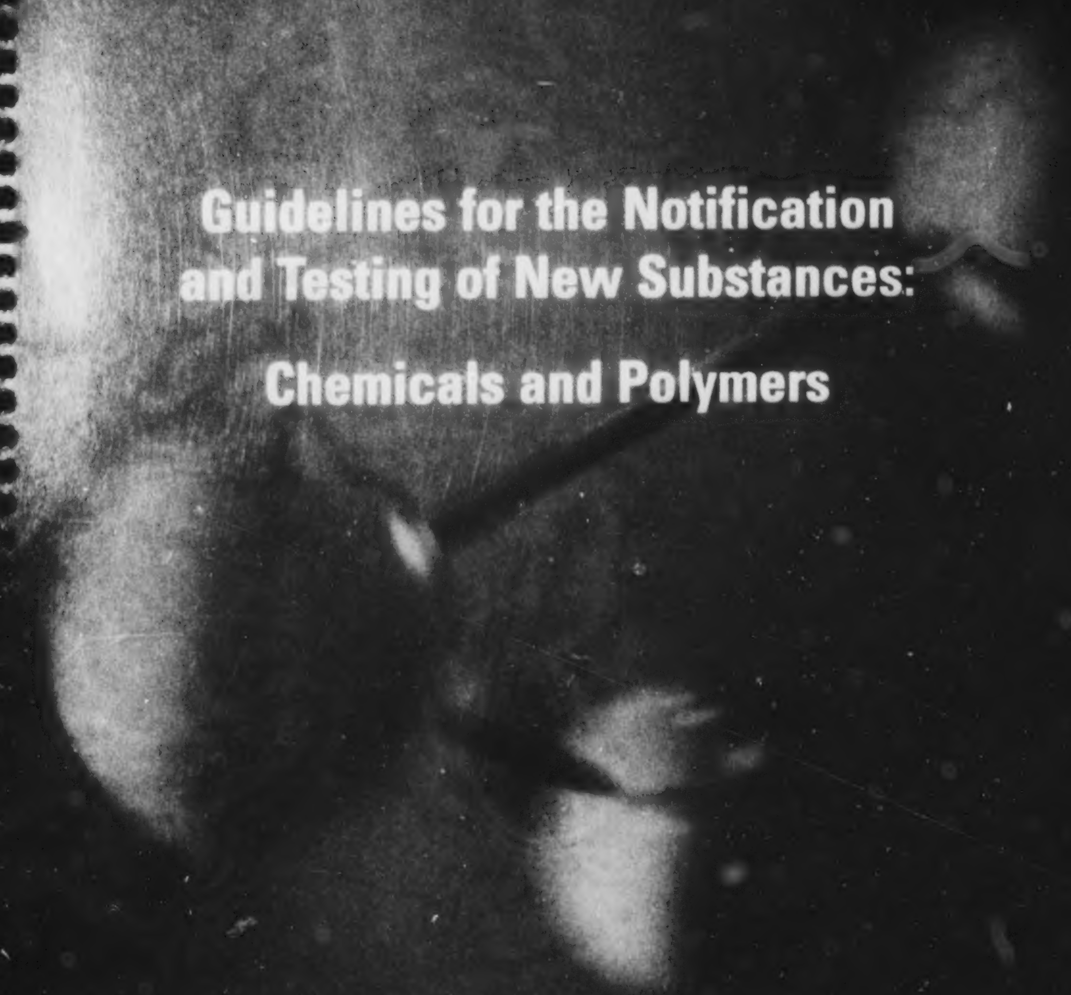
substances nouvelles



Guidelines for the Notification and Testing of New Substances:

Chemicals and Polymers

Pursuant to
The New Substances Notification Regulations
of the
Canadian Environmental Protection Act, 1999

August 2001 — EPS M-453

Canada

Health Canada Santé Canada

102-01925/

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Although care has been taken to ensure that these Guidelines accurately reflect requirements prescribed in the Canadian Environmental Protection Act, 1999 (CEPA, 1999) *and the New Substances Notification Regulations (NSNR), notifiers are advised that, should any inconsistencies be found, CEPA, 1999 and the NSNR will prevail.*

Abstract

This document has been prepared to assist individuals (notifiers) responsible for complying with the New Substances Notification Regulations of the *Canadian Environmental Protection Act, 1999*.

These guidelines explain, in detail, how notifiers determine whether a substance is subject to notification under the New Substances Notification Regulations and identify the applicable information requirements. In addition, these guidelines provide step-by-step instructions for the completion of a New Substances Notification (NSN) Form, elaborate the technical considerations of the information requirements, identify appropriate test procedures and practices, and outline how confidential information should be treated. These guidelines conclude with an explanation of how Environment Canada and Health Canada assess the information submitted in an NSN, and the implications of the assessment decisions for notifiers.

Résumé

Le présent document a été préparé pour aider les personnes (déclarants) responsables d'observer le *Règlement sur les renseignements concernant les substances nouvelles* de la *Loi canadienne sur la protection de l'environnement, 1999*.

Les directives expliquent en détail aux déclarants comment établir si une substance doit être déclarée en vertu du Règlement et comment déterminer les renseignements à fournir. Elles renferment aussi des instructions détaillées pour remplir la Déclaration de substance nouvelle (DSN), des précisions sur les renseignements techniques exigés, des informations sur les procédés et méthodes d'essai appropriés, ainsi qu'un aperçu du mode de traitement des renseignements confidentiels. Finalement, on explique comment Environnement Canada et Santé Canada évaluent les renseignements fournis dans la DSN et les implications des décisions d'évaluation pour les déclarants.

Table of contents

COMMENTS AND INQUIRIES 3

ABSTRACT 4

RÉSUMÉ 5

LIST OF ACRONYMS 11

HOW TO USE THESE GUIDELINES 13

SECTION 1 - INTRODUCTION 15

1.1 THE CANADIAN ENVIRONMENTAL PROTECTION ACT 15
1.2 OVERVIEW OF NEW SUBSTANCES PROVISIONS UNDER THE CANADIAN ENVIRONMENTAL PROTECTION ACT, 1999 15
1.3 NEW SUBSTANCES NOTIFICATION REGULATIONS 16
1.4 INSPECTION AND ENFORCEMENT 17
1.4.1 Penalties 17

SECTION 2 - SUBSTANCES SUBJECT TO NOTIFICATION 18

2.1 DEFINITION OF "SUBSTANCE" 18
2.2 DEFINITION OF "NEW" SUBSTANCE 18
2.2.1 Substances Considered to be on the Domestic Substances List 19
2.3 SIGNIFICANT NEW ACTIVITY (SNAC) NOTICE 20
2.4 SUBSTANCES NOT SUBJECT TO THE NEW SUBSTANCES PROVISIONS OF THE CANADIAN ENVIRONMENTAL PROTECTION ACT, 1999 20
2.4.1 Exclusions from the Definition of a Substance 20
2.4.2 New Substances Not Requiring Notification 22
2.4.3 Substances Carried Through Canada 24
2.4.4 Polymers and biopolymers Subject to the "Two Percent Rule" 24
2.4.5 Proteins subject to the "Two Percent Rule" 25
2.5 NOTIFIABLE TRANSITIONAL SUBSTANCES 25
2.6 NOTIFICATION OF BIOCHEMICALS OR BIOPOLYMERS FIRST MANUFACTURED OR IMPORTED BETWEEN JULY 1, 1994 AND SEPTEMBER 1, 1997 26

SECTION 3 - INFORMATION REQUIREMENTS 27

3.1 CLASSIFICATION OF SUBSTANCES 27
3.1.1 Chemicals and biochemicals 27
3.1.2 Polymers and biopolymers 27
3.1.3 Products of Biotechnology 28
3.2 HOW TO IDENTIFY THE REQUIRED NOTIFICATION INFORMATION 28
3.2.1 Chemicals and biochemicals 29
3.2.2 Polymers and Biopolymers 38
3.3 SUBSTANCES ON THE NON-DOMESTIC SUBSTANCES LIST 47
3.4 TRANSITIONAL SUBSTANCES 48
3.4.1 Chemicals and Polymers 49
3.4.2 Biochemicals and Biopolymers 50
3.5 ANNUAL AND ACCUMULATED QUANTITIES 51
3.6 WHEN TO NOTIFY THE GOVERNMENT 51
3.6.1 Notification of Substances Exceeding Trigger Quantities During the Transitional Period 51
3.6.2 Notification of Substances that Exceed Trigger Quantities After the Transitional Period 54
3.7 NOTIFICATION OF PRODUCT DEVELOPMENT SUBSTANCES 55
3.8 FOR MORE INFORMATION ABOUT THE NSNR 55

3.9 SUPPORTING DOCUMENTATION 56
  3.9.1 Notification Forms and Guidelines 56
  3.9.2 Inventories 57

SECTION 4 - TECHNICAL INFORMATION REQUIREMENTS 59

4.1 SUBSTANCE IDENTITY INFORMATION 59
  4.1.1 Substance Name 59
  4.1.2 Masked Name 60
  4.1.3 Chemical Abstracts Service Registry Number 60
  4.1.4 International Union of Biochemistry and Molecular Biology Numbers 61
  4.1.5 Structural Formula 61
  4.1.6 Molecular Formula 62
  4.1.7 Molecular Weight 62
  4.1.8 Impurities and their Concentration 62
  4.1.9 Additives and their Concentration 62
  4.1.10 Monomers and Reactants 62
  4.1.11 Material Safety Data Sheet 62
4.2 EXPERIMENTAL DATA 63
  4.2.1 Physical–Chemical Data — Chemicals and Biochemicals 63
  4.2.2 Physical–Chemical Data — Polymers and Biopolymers 64
  4.2.3 Toxicological Data 65
  4.2.4 Ecotoxicological Data 66
4.3 EXPOSURE INFORMATION 67
  4.3.1 Manufacture Information 67
  4.3.2 Import Information 68
  4.3.3 Specific Use Information 68
  4.3.4 Distribution, Storage, and Handling Information 68
  4.3.5 Disposal Information 69
  4.3.6 Environmental Release Information 69
  4.3.7 Human Exposure Information 70
  4.3.8 Analytical Test Methods 71
4.4 OTHER AGENCIES NOTIFIED 71
4.5 ADDITIONAL INFORMATION 71
4.6 INTERPRETATION OF "PERSON" - SECTION 81 OF THE CEPA, 1999 72
4.7 INFORMATION SHARING AGREEMENTS 73

SECTION 5 - TEST PROCEDURES AND PRACTICES 74

5.1 ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT TEST GUIDELINES 74
5.2 GOOD LABORATORY PRACTICE 74
5.3 HEALTH PROTECTION BRANCH MUTAGENICITY TEST GUIDELINES 74
5.4 ALTERNATIVE PROCEDURES 75
  5.4.1 Alternative Test Protocols 75
  5.4.2 Structure–Activity Relationships 78
  5.4.3 Other Calculation Methods 81
5.5 TEST DATA ON UVCBS AND IMPURE SUBSTANCES 81
5.6 SOURCES OF TEST METHODS 81

SECTION 6 - WAIVER OF INFORMATION REQUIREMENTS 84

6.1 INTRODUCTION 84
6.2 WAIVERS REQUESTED UNDER PARAGRAPH 81(8)(A) OF THE CANADIAN ENVIRONMENTAL PROTECTION ACT, 1999 85
6.3 WAIVERS REQUESTED UNDER PARAGRAPH 81(8)(B) OF THE CANADIAN ENVIRONMENTAL PROTECTION ACT, 1999 85
6.4 WAIVERS REQUESTED UNDER PARAGRAPH 81(8)(C) OF THE CANADIAN ENVIRONMENTAL PROTECTION ACT, 1999 87

SECTION 7 - PRE-NOTIFICATION CONSULTATION 88

SECTION 8 - PREPARING A NEW SUBSTANCES NOTIFICATION 89

8.1 THE NOTIFICATION FORM 89
8.2 PROPRIETARY INFORMATION - FOREIGN SUPPLIER SUBMISSIONS 89
8.3 COMPLETING THE NEW SUBSTANCES NOTIFICATION FORM 90
  8.3.1 Part A - Administrative Information and Substance Identity 90
  8.3.2 Part B - Technical Data 93

SECTION 9 - CONFIDENTIAL INFORMATION 96

9.1 CLAIMING CONFIDENTIALITY 96
9.2 INFORMATION SUPPLEMENTAL TO A CONFIDENTIALITY CLAIM 96
  9.2.1 General Confidentiality Claims 96
  9.2.2 Confidential Substance Identity Claims 97
9.3 DETERMINING THE PRESENCE OF CONFIDENTIAL SUBSTANCES ON LISTS 98

SECTION 10 - PROCESSING A NOTIFICATION 100

10.1 RECEIPT OF A NEW SUBSTANCES NOTIFICATION 100
  10.1.1 Assessment "Time Clock" 100
  10.1.2 New Substances Notification Reference Number 100
10.2 CORRESPONDENCE 101
  10.2.1 Acknowledgement 101
  10.2.2 Notice of Interruption or Rejection 101
  10.2.3 Notice of Extension of Assessment Period 101
  10.2.4 Statement of Assessment Conclusions 102
10.3 ASSESSMENT OF THE NOTIFICATION 102
  10.3.1 Information Review 102
  10.3.2 Assessment for Toxicity 102
10.4 ACTION TAKEN AFTER AN ASSESSMENT 103
  10.4.1 Control Measures 103
  10.4.2 Additions to the Domestic Substances List 104
10.5 PROGRAM OVERVIEW 105

SECTION 11 - POST-NOTIFICATION RESPONSIBILITIES 107

11.1 CORRECTION OF INFORMATION 107
11.2 NOTICE OF EXCESS QUANTITY 107
11.3 SECTION 70 OF THE CANADIAN ENVIRONMENTAL PROTECTION ACT, 1999 108

APPENDIX 1 - SCHEDULES OF INFORMATION UNDER THE NSNR 109

APPENDIX 2 - ENVIRONMENT CANADA REGIONAL OFFICES 143

APPENDIX 3 - NAMING SUBSTANCES 145

APPENDIX 4 - LOCATING CHEMICAL ABSTRACTS SERVICE REGISTRY NUMBERS 175

APPENDIX 5 - EXAMPLES OF WAIVER CONDITIONS 179

APPENDIX 6 - POLYMER/BIOPOLYMER TEST METHODS 184

APPENDIX 7 - MASKING OF SUBSTANCE NAMES 194

APPENDIX 8 - GLOSSARY 211

List of Tables

1 Notification Periods for Chemicals and Polymers that Exceeded Trigger Quantities during the Transitional Period 51

1.1 Notification Periods for Biochemicals and Biopolymers that Exceed Trigger Quantities during the Transitional Period 51

2 Notification Periods for Substances that Exceed Trigger Quantities after the Transitional Period 54

3 Physical-Chemical Test Methods (Chemicals and Biochemicals) 76

4 Physical-Chemical Test Methods (Polymers and Biopolymers) 76

5 Toxicological Test Methods (Chemicals/Biochemicals and Polymers/Biopolymers) 77

6 Ecotoxicological Test Methods (Chemicals/Biochemicals and Polymers/Biopolymers) 77

7 Specific Substance Names for Well-defined Substances 142

8 Common Abbreviations that can be used to Indicate Structural Information 143

9 Representations for Nonylphenol 144

10 Specific Substance Names for Complex and Variable Substances ....155 -156

11 List of Common Chemical Structural Units ....190 -199

List of Figures

Figure 1 Notification Requirements for New Chemicals/Biochemicals 31
Figure 2 Scheme A: Transitional Chemicals/Biochemicals 32-33
Figure 3 Scheme B: Product Development Chemicals/Biochemicals..........................34
Figure 4 Scheme C: Export Only Chemicals/Biochemicals 35
Figure 5 Scheme D: Site-limited Intermediate Chemicals/Biochemicals 36
Figure 6 Scheme E: All other Chemicals/Biochemicals 37
Figure 7 Notification Requirements for New Polymers/Biopolymers: Scheme A........44
Figure 8 Notification Requirements for New Polymers/Biopolymers: Scheme B........45
Figure 9 Overview of New Substances Notification Assessment Process 105

List of Acronyms

ASTM ---------------- American Society for Testing and Materials
CA---------------------- Chemical Abstracts
CAS-------------------- Chemical Abstracts Service
CBI--------------------- Confidential Business Information
CEC ------------------- Commission of European Communities
CEPA, 1999 --------- *Canadian Environmental Protection Act*, 1999
CTFA ------------------ The Cosmetic, Toiletry and Fragrance Association
DSL -------------------- Domestic Substances List
EC ---------------------- Environment Canada
ECOIN ----------------- European Core Inventory
EINECS--------------- European Inventory of Existing Commercial Chemical Substances
FIFRA ----------------- *Federal Insecticide Fungicide and Rodenticide Act*
GC --------------------- Gas Chromatography
GLP-------------------- Good Laboratory Practice
GPC ------------------- Gel Permeation Chromatography
HPB-------------------- Health Protection Branch
HPLC------------------ High Performance Liquid Chromatography
INN-------------------- International Non-proprietary Names
IR ---------------------- Infrared
ISO-------------------- International Organization for Standardization
ISA -------------------- Information Sharing Agreement
IUPAC----------------- International Union of Pure and Applied Chemistry
IUBMB --------------- International Union of Biochemistry and Molecular Biology
M_n ---------------------- Number-average Molecular Weight
M_w ---------------------- Weight-average Molecular Weight
MSDS ----------------- Material Safety Data Sheet
NDSL------------------ Non-domestic Substances List
NMR ------------------ Nuclear Magnetic Resonance
NSN ------------------- New Substances Notification
NSNR ----------------- New Substances Notification Regulations
OECD ----------------- Organization for Economic Cooperation and Development
OoE ------------------- Office of Enforcement
PIN -------------------- Product Identification Number
QSAR ----------------- Quantitative Structure-Activity Relationship
RI ---------------------- Refractive Index
RTECS---------------- Registry of Toxic Effects of Chemical Substances
SAR-------------------- Structure-Activity Relationship
SFC-------------------- Supercritical Fluid Chromatography
SNAc ----------------- Significant New Activity
STN------------------- Scientific and Technical Information Service
TLC ------------------- Thin Layer Chromatography
TSCA----------------- *Toxic Substances Control Act*

USAN ----------------- United States Adopted Names
U.S. EPA ------------- United States Environmental Protection Agency
USP-------------------- United States Pharmacopeial Convention
UV---------------------- Ultraviolet
UVCB ----------------- Unknown or Variable composition Complex reaction products and
------------------------- Biological materials
WHO ------------------ World Health Organization

How to Use these Guidelines

These Guidelines have been prepared for the benefit of individuals responsible for complying with the information provisions of the New Substances Notification Regulations of the *Canadian Environmental Protection Act, 1999* (CEPA, 1999). It is recommended that the entire text be read before a notification dossier is prepared. A sequential review of the Sections will allow the reader to focus on requirements specific to their circumstance. The key to avoiding unnecessary delays or expenses when preparing a notification is to understand thoroughly the new substances notification program. These Guidelines are organized into eleven Sections:

1. **Introduction** - explains the purpose, statutory powers, and features of the new substances notification program.

2. **Substances Subject to Notification** - helps to determine whether the substance to be imported, manufactured or used must be notified.

3. **Information Requirements** - if the substance must be notified, this Section helps identify the appropriate notification group, associated information that must be included in the notification dossier, and the time available to provide the information to Environment Canada.

4. **Technical Information Requirements** - describes the meaning and intent of each information requirement, and elaborates exemptions for specific data requirements.

5. **Test Procedures and Practices** - provides guidance on acceptable test methods and "alternate" information.

6. **Waiver of Information Requirements** - describes features of subsection 81(8) of the CEPA, 1999, which provides for the waiver of information requirements when one of several criteria is met.

7. **Pre-notification Consultation** - encourages consultation with government officials to resolve notification issues while the notification dossier is being prepared.

8. **Preparing a New Substances Notification** - provides instructions for completing a NSN Form.

9. **Confidential Information** - describes issues pertaining to confidential business information, such as confidentiality claims, masking of substance identities, and

determining the presence of confidential substances on the Domestic and Non-domestic Substances Lists.

10. **Processing a Notification** - explains what happens after a notification is received, including how a notification is processed and reviewed, and the types of correspondence that will be sent by the government.

11. **Post-notification Responsibilities** - reviews obligations of notifiers after a notification has been submitted.

Further clarification on any topic covered by these guidelines can be obtained from the New Substances Notification Information Line at (800)567-1999 or (819)953-7156 (outside Canada), by facsimile at (819)953-7155, or email: NSN-infoline@ec.gc.ca.

Section 1 - Introduction

These Guidelines provide detailed information on the chemical[1], biochemical, polymer and biopolymer portions of the New Substances Notification Regulations to clarify the obligations of notifiers and to assist with the preparation of notifications. Information pertaining to substances that are living organisms can be found in the *Guidelines for the Notification and Testing of New Substances: Organisms.*

1.1 The Canadian Environmental Protection Act

The *Canadian Environmental Protection Act, 1999 (CEPA, 1999)* is a modernized statute that addresses the responsibility of the Canadian Government to identify potential adverse effects on human health and the environment from chemicals and other substances. CEPA, 1999 provides the federal government the authority to address pollution problems and takes a pollution prevention approach by requiring that substances be identified and assessed, prior to market introduction (new substances) to determine whether they are "toxic" or capable of becoming toxic in the context of the statute. "Toxic", as defined in CEPA, 1999, refers to risk to human health or the environment. The Act also provides for a comprehensive "cradle-to-grave" management approach for chemicals and other substances.

Whereas new chemicals, polymers and products of biotechnology (both animate and inanimate) were all dealt with together by the predecessor to CEPA, 1999, animate products of biotechnology are addressed separately in Part 6 of the Act. New chemicals, new polymers and new inanimate products of biotechnology are dealt with under Part 5 of CEPA, 1999.

1.2 *Overview of New Substances Provisions Under the* Canadian Environmental Protection Act, 1999

Substances that are "new" to Canadian commerce fall under the purview of Parts 5 and 6 of the CEPA, 1999. New substances that are chemicals, polymers and inanimate products of biotechnology are covered in Part 5 of the CEPA, 1999, whereas Part 6 of the CEPA, 1999 deals with new substances that are animate products of biotechnology.

The CEPA, 1999 approach to the control of new substances is both proactive and preventative, employing a pre-import or pre-manufacture notification and assessment process. When this process identifies a new substance that may pose a risk to health or the environment, the Act empowers Environment Canada to intervene prior to or during the earliest stages of its introduction to Canada. This ability to act early makes the new substances program a unique and essential component of the federal management of toxic substances.

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[1] "Chemical" refers to a substance other than a polymer or a product of biotechnology .

Substances determined to be or suspected of being toxic or capable of becoming toxic may be controlled as necessary, including prohibiting their import or manufacture. The assessment process begins when Environment Canada receives a New Substances Notification prepared by the company or individual that proposes to import or manufacture a new substance or use it for a Significant New Activity (SNAc). New Substances Notifications must contain all required administrative and technical data and must be provided to Environment Canada by a prescribed date before manufacture, import or use for a SNAc. Notification information is jointly assessed by the Departments of Environment and Health to determine whether there is a potential for adverse effects of the substance on the environment and human health. This assessment, which must be completed within a specified time, will result in:

(a) a determination that the substance is not suspected of being toxic or capable of becoming toxic;

(b) a suspicion that the substance is toxic or capable of becoming toxic, which may require: (i) controls on import and manufacture, (ii) prohibition of import and manufacture, or (iii) prohibition pending submission and assessment of additional information determined to be required by the Departments;

(c) limiting the purpose for which a substance may be used to permit the waiver of information requirements defined under Paragraph 81(8)(b) of the CEPA, 1999; or

(d) a suspicion that a significant new activity in relation to the substance may result in the substance becoming toxic. In such instances, a SNAc Notice will be issued for the substance.

1.3 New Substances Notification Regulations

The main regulatory features of the program are: establishment of categories or groups of substances; identification of administrative and information requirements; timing of notification before import or manufacture or use outside the scope of a SNAc Notice; requirements for the Departments to assess information within a set time; and specification of conditions, test procedures, and laboratory practices to be followed when developing test data.

To meet the need for evaluating different categories of substances, information requirements are determined by separating substances into categories and notification groups. In essence, substances are first generically categorized (e.g., polymers, products of biotechnology), and then categorized by notification group based on factors such as: volume of import/manufacture, or proposed use (e.g., research and development). This system of notification groups allows the government to match information requirements with anticipated concerns about quantities and characteristics of specific groups of substances.

Under the NSNR, any person in Canada who manufactures or imports substances subject to notification must provide a notification package to Environment Canada. This package must contain all information specified in the NSNR. Based on this information, Environment Canada and Health Canada will conduct an assessment of whether the substance is likely to harm the environment, the environment upon which human life depends, or human life and health.

Parts I, II and III of the NSNR, covering substances that are chemicals or polymers, have been in effect since July 1, 1994. The amendments to the NSNR, covering substances that are living organisms, or products of micro-organisms (biochemicals and biopolymers), have been in effect since September 1, 1997.

1.4 Inspection and Enforcement

Under the *Canadian Environmental Protection Act, 1999*, Environment Canada enforcement officers may carry out inspections in order to ensure that persons subject to the Act are in compliance with all regulatory and legislative provisions. In verifying compliance with these Regulations, Enforcement Officers will abide by the **Enforcement and Compliance Policy** of the CEPA, 1999, which was established to ensure that the Act is applied throughout Canada in a manner that is fair, predictable and consistent.

Where there is sufficient evidence of a violation, Enforcement Officers will take the necessary and appropriate measures in accordance with the criteria set out in the Policy. The possible responses for dealing with violations range from warnings to prosecution. Other available measures are discussed in further detail in the Enforcement and Compliance Policy, and can be found at http://www.ec.gc.ca/enforce/homepage/cepa/english/99policy.pdf.

1.4.1 Penalties

With respect to the NSNR, anyone convicted of an indictment under CEPA, 1999 is liable to a fine not exceeding one million dollars and/or imprisonment for a term not exceeding three years. Upon summary conviction, anyone who commits an offense is liable to pay a fine of up to $200,000 and/or serve up to six months in prison.

Section 2 - Substances Subject to Notification

Notification is required if the material proposed for import or manufacture is subject to the provisions of the Substances and Activities New to Canada portion of the CEPA, 1999 (sections 80 to 89). Materials that require notification are: (1) "substances" as defined in the Act; (2) "new" in the context of the CEPA, 1999; and (3) neither excluded nor exempted from notification as specified in section 3 or subsection 81(6) of the CEPA, 1999.

2.1 Definition of "Substance"

For the purposes of the CEPA, 1999, "substance" has been defined in section 3 of the Act as:

"any distinguishable kind or organic or inorganic matter, whether animate or inanimate, and includes

(a) any matter that is capable of being dispersed in the environment or of being transformed in the environment into matter that is capable of being so dispersed or that is capable of causing such transformations in the environment;

(b) any element or free radical;

(c) any combination of elements of a particular molecular identity that occurs in nature or as a result of a chemical reaction; and

(d) complex combinations of different molecules that originate in nature or are the result of chemical reactions but that could not practicably be formed by simply combining individual constituents."

In some instances, materials derived from natural sources and complex reactions cannot be characterized in terms of constituent chemical compounds because their composition is too complex or variable. These materials are commonly referred to as Unknown or Variable composition Complex reaction products and Biological materials (UVCBs) and are considered a single substance for notification purposes.

2.2 Definition of "New" Substance

The Domestic Substances List (DSL) is the sole basis for determining whether a substance is new for the purposes of the CEPA, 1999. Substances on the DSL are considered to exist in Canadian commerce and do not require notification unless they are proposed for a SNAc as indicated on the DSL. Substances not on the DSL are considered to be new to Canada and are subject to notification. The DSL includes the list, published on May 4, 1994 in Part II of the *Canada Gazette*, and all additions or deletions subsequently published in the *Canada Gazette*. Substances may be included on the DSL based on either:

(a) commercial use in Canada between January 1, 1984 and December 31, 1986 (subsection 66(1) of the CEPA, 1999); or

(b) the government has received all the prescribed information under Section 81 of the CEPA, 1999, and an assessment by the Departments has determined that no controls should be imposed and that the import or manufacture has commenced after the most comprehensive notification package was assessed, or exceeded the prescribed volumes (Section 87 of the CEPA, 1999).

Information on obtaining and searching the DSL for specific substances is described in Subsection 3.9.2 of these Guidelines.

2.2.1 Substances Considered to be on the Domestic Substances List

2.2.1.1 Hydrates. Hydrates of a substance or hydrated ions formed by association of a substance with water are considered to be a mixture of that substance and water. Therefore, if the anhydrous form is present on the DSL, all hydrated forms are also considered to be present on the DSL, and thus are not notifiable substances.

Metallic hydroxides, often termed metal hydrates, do not contain water of hydration and are not considered hydrates for notification purposes. Such substances must be notified if not present on the DSL. An example of a metal hydroxide is copper hydroxide, $Cu(OH)_2$.

2.2.1.2 Homogeneous and Heterogeneous Alloys. Homogeneous and heterogeneous alloys are considered mixtures and should not be notified. Alloys that are solid or liquid mixtures of two or more metals, or are mixtures of one or more metals with certain nonmetallic elements (e.g., certain carbon steels), are considered mixtures and are not notifiable. Intermetallic compounds of well-defined stoichiometry are not considered alloys and should be notified.

2.2.1.3 Special Categories. Substances that can be categorized within one of the following special categories are considered to be present on the DSL and are not notifiable:

(a)	Glass, oxide, chemicals	[65997-17-3*]
(b)	Frits, chemicals	[65997-18-4*]
(c)	Ceramic materials and wares, chemicals	[66402-68-4*]
(d)	Steel manufacture, chemicals	[65997-19-5*]
(e)	Cement, alumina, chemicals	[65997-16-2*]
(f)	Cement, portland, chemicals	[65997-15-1*]

Definitions of these categories are found in their respective DSL listing or can be obtained by contacting the NSN Information Line at:

(800) 567-1999 (within Canada) or
(819) 953-7156 (outside Canada).

2.2.1.4 Substances Occurring in Nature. Substances occurring in nature are considered to be on the DSL, although they may not be listed individually. These substances are defined as naturally occurring, and are: unprocessed; processed only by manual, gravitational, or mechanical means, by dissolution in water, by flotation, or by heating solely to remove water; or extracted from air by any means.

2.3 Significant New Activity (SNAc) Notice

A SNAc Notice essentially triggers submission of information for specific new activities. When a SNAc Notice is issued, the substance is added to the DSL with a SNAc flag, once it meets all eligibility criteria. In this case, all importers, manufacturers and users shall submit the information specified within the SNAc Notice if they want to manufacture, import or use the substance outside the scope of activities specified in the SNAc Notice.

When a SNAc Notice is issued but the substance is not added to the DSL because it does not meet the eligibility criteria, all importers/manufacturers shall comply with the NSNR by submitting the appropriate prescribed requirements. In addition, no one shall use the substance outside the scope of activities specified in the SNAc Notice before submitting the information specified within the SNAc Notice and before it has been assessed.

When information is submitted in compliance of a SNAc Notice, Environment Canada and Health Canada must assess it within the time period specified by the SNAc Notice. The SNAc Notice may then be modified, or other control measures as stated previously, can be imposed if necessary.

2.4 Substances not Subject to the New Substances Provisions of the Canadian Environmental Protection Act, 1999

2.4.1 Exclusions from the Definition of a Substance

For the purposes of the Substances New to Canada portion of the CEPA, 1999, limitations on the statutory definition of "substance" are imposed under section 3 of the CEPA, 1999. Substances described by the following definitions are not subject to the New Substances provisions of the CEPA, 1999 and are therefore excluded from notification.

2.4.1.1 "Any mixture that is a combination of substances and does not itself produce a substance that is different from the substances that were combined".

Mixtures that are deliberately prepared formulations, or reaction mixtures that are fully characterized in terms of constituent substances (except for minor impurities) are not considered substances and, consequently, do not require notification. Examples include paints and coatings, blended fuels, and solvent mixtures. However, if any constituent of a mixture is a new substance, that constituent is considered to be a notifiable substance.

Mixtures derived from natural sources or complex reactions that cannot be characterized because their composition is too complex or variable (i.e., UVCBs) are considered single substances and are subject to notification.

2.4.1.2 "Any manufactured item formed into a specific physical shape or design during manufacture and has, for its final use, a function or functions dependent in whole or in part on its shape or design". Materials that meet the above criteria for a manufactured item will possess a definite shape or design necessary to its final function.

Shape describes the macrostructure, i.e., the physical three-dimensional structure of the final item. Items whose end use depends on final manufactured shape include clothing, storage containers, furniture, tiles, and electrical wire. However, solid substances formed into a particular shape to meet subsequent processing and manufacturing requirements, rather than final use, (e.g., metal ingots and polymer pellets) are not considered to meet this definition of manufactured item and must be notified.

Design refers to the organization or arrangement of the solid components within the macrostructure (e.g., the weave of fabric and carpeting, layering of plywood, or binding of paper fibres) that is not altered in any subsequent processing. For example, fabric retains its final physical design regardless of whether it is a bolt of cloth or an article of clothing because the manufacture of the clothing does not alter the design (weave) of the cloth.

Manufactured items that undergo subsequent chemical reactions may still be excluded from the definition of a substance if they:

(a) undergo surface chemical reactions only to increase stiffness, strength, or flame resistance, to alter colour, or to improve resilience or bacterial resistance, while maintaining their bulk structure (e.g., brake linings, fibres, leather, paper and yarns; and dyed fabrics); or

(b) undergo a change in chemical composition that is intrinsic to the intended end use (e.g., matches, flares, photographic films, and batteries).

Fluids (e.g., gases, liquids, waxes, solutions, and suspensions) and particles (e.g., dusts, powders, dispersions, granules, lumps, flakes, and aggregates of unspecified size) are not considered items even if the usefulness of the product depends on the particle's shape. However, a fluid or particulate matter that remains contained within a manufactured item during normal use is considered an integral part of that item, and is thus not notifiable. Furthermore, a fluid or particulate matter is considered an integral part of the item if the normal release of the fluid or particulate matter is controlled and non-dispersive and is specific to the end use of the item (e.g., lubricants in motor vehicles and ink in pens, stamp pads, and typewriter ribbons).

2.4.1.3 "Any animate matter that is, or any complex mixtures of different molecules that are, contained in effluents, emissions or wastes that result from any work, undertaking or activity". Material contained in effluents, emissions, and wastes is excluded from the statutory definition of a new substance. However, if a material in this category is subsequently used as a commercial product, it will be considered a notifiable substance and, if not listed on the DSL, will be subject to the NSNR.

2.4.2 New Substances Not Requiring Notification

Subsection 81(6) of the CEPA, 1999 establishes criteria for new substances that do not require notification. Substances described in this section are not subject to the New Substances Notification Regulations.

2.4.2.1 "A substance that is manufactured or imported for a use that is regulated under any other Act of Parliament that provides for notice to be given before the manufacture, import or sale of the substance and for an assessment of whether it is toxic or capable of becoming toxic".

Paragraph 81(6)(a) of the CEPA, 1999 sets out criteria for exempting new substances regulated by another federal Act and Regulation from the notification obligations of the CEPA, 1999. The criteria to be met by the other Act and Regulation are that it must:

"provide for notice to be given before the manufacture, import, or sale of the substance and for an assessment of whether it is toxic or capable of becoming toxic".

Who determines whether these criteria have been met?

Under subsection 81(7) of the CEPA, 1999, the Governor in Council (which is a committee of Cabinet) has the exclusive authority for determining whether these criteria are met by another federal Act and Regulation, and if so, to list them in Schedule 2 of the CEPA, 1999. Once added to Schedule 2, substances regulated by the listed Acts are exempt from the "Substances New to Canada" reporting requirements of the CEPA, 1999. This new provision is meant to ensure there is a federal assessment consistent with CEPA, 1999, that includes environmental and human health aspects of all new substances, prior to manufacture, import or sale, and to avoid unnecessary duplication of regulation.

Subsection 81(7) came into force September 13, 2001.

Potential notifiers of new substances regulated under Acts and Regulations other than CEPA and the NSNR should monitor Federal Government websites and/or the *Canada Gazette* to determine whether the use for which the substance is proposed remains under the jurisdiction of another federal Act or defaults to the CEPA, 1999.

Precursor materials not listed on the DSL and excluded from the scope of other Acts or Regulations, including isolated reaction intermediates, feedstocks and other starting materials used in the manufacture of any new substance are subject to notification under the CEPA, 1999.

2.4.2.2 "Transient reaction intermediates that are not isolated and are not likely to be released into the environment". Transient reaction intermediates are substances produced within a sequence of chemical reactions between the starting materials and the end product and are:

(a) contained in a reaction vessel or a closed manufacturing system (including process holding tanks) located within a single building or single process area;

(b) intended to be fully consumed in the course of the chemical reaction;

(c) part of an uninterrupted manufacturing process (i.e., at any one time, starting materials or intermediates within the reaction sequence are being processed, except in the event of an unscheduled shutdown); and

(d) not likely to be released into the environment during normal operations, and measures are in place to minimize releases during accidental breaches of the closed manufacturing system.

Companies are advised to maintain technical data (process and environmental release information) to support their exemption on the basis of the statements "reaction vessel or closed manufacturing system", "single process area", "fully consumed", "uninterrupted manufacturing process", and "not likely to be released". This information only needs to be retained while the company is actively manufacturing the transient reaction intermediate substance.

2.4.2.3 "Impurities, contaminants and partially unreacted materials the formation of which is related to the preparation of a substance". Impurities and contaminants are substances that are normally found in minimal concentration in the starting materials or are the result of secondary reactions that occur during the manufacturing process. These substances, and partially unreacted starting materials that are present in the final product, are the direct result of the preparation, are not necessary to the end use of the product, have not been intentionally added to the substance, and do not enhance the commercial value of the substance.

2.4.2.4 *"Substances produced when a substance undergoes a chemical reaction that is incidental to the use to which the substance is put or that results from storage or from environmental factors".* Examples of incidental reaction products include substances formed from chemical reactions during:

(a) exposure to environmental factors such as air, moisture, microbial organisms, and sunlight (substances produced from deliberate reactions with water are not exempt, e.g., metal hydroxides formed from a metal oxide and water);

(b) storage (e.g., partial polymerization of drying oils);

(c) the intended use of a substance or mixture (e.g., adhesives, paints, cleansers, combustion products from fuels, fuel additives, and water softeners); and

(d) the blending of a formulation when there is no intention to produce new substances and any ensuing chemical reactions do not enhance the commercial value of the formulation (e.g., blending monomers to a precise ratio for customer convenience would not result in a notifiable substance even if some reactions occurred; however, intentional manufacture of a pre-polymer to satisfy a customer's processing specifications would produce a notifiable substance).

2.4.2.5 *"A substance that is manufactured or imported in a quantity that does not exceed the maximum quantity prescribed as exempt from this section (section 81 of the CEPA, 1999)".* Substances manufactured or imported in quantities that do not exceed the minimum notification quantities do not require notification. The specific minimum notification quantities for each information schedule can be found in Section 3 of these Guidelines.

2.4.3 Substances Carried Through Canada

The New Substances Notification Regulations do not apply to a substance that is loaded on a carrier outside Canada and moved through Canada to a point outside Canada. This exclusion applies even if there is a change of carrier during transit. However, if a substance is brought into Canada and stored for subsequent distribution, the substance is subject to the New Substances Notification Regulations.

2.4.4 Polymers and biopolymers Subject to the "Two Percent Rule"

A polymer or biopolymer, manufactured by modifying the formulation of a polymer or biopolymer specified on the DSL by adding reactants, none of which constitutes more than two percent by weight of the polymer or biopolymer, is exempt from notification. Note that the term modifying refers to the amount of additional reactant that has been incorporated into the structure of the polymer or biopolymer, or the amount charged to the vessel.

For biopolymers, monomer units and reactants are considered to be the repeating units within the polymeric substance which are produced *in situ* by the micro-organism, or are added to the reaction vessel.

2.4.5 Proteins subject to the "Two Percent Rule"

In some instances, a protein that is not on the DSL can be considered to be substantially equivalent to a protein that is listed on the DSL. Proteins that are substantially equivalent are not subject to the New Substances Notification Regulations.

A protein is considered to be substantially equivalent if:

(i) the function of the protein has not been changed from the protein listed on the DSL; and,

(ii) (a) the protein has 98% amino acid sequence homology with the listed protein, based on amino acid or DNA sequence; or

(b) the protein is 98% identical to the listed protein based on all of the following items: molecular weight, isoelectric point (pI), amino acid composition, peptide map, and N-terminal sequence.

Point (ii) (b) does not apply to enzymes.

In certain circumstances, substantial equivalence could be applicable beyond the established 2% limit. A scientifically defensible rationale for substantial equivalence above the 2% limit must be presented to Environment Canada which will determine whether it is applicable in those circumstances.

2.5 Notifiable Transitional Substances

Substances not listed on the DSL, and manufactured or imported in a quantity greater than 20 kg in any calendar year during the transitional period (between January 1, 1987 and July 1, 1994), are subject to the transitional provisions of subsection 81(2). Subsection 81(2) allows the manufacture or import of these "transitional substances" to continue after July 1, 1994, if the prescribed information was provided to Environment Canada before a prescribed date (refer to Subsection 3.6).

For biochemicals:

Transitional biochemicals may not be treated as "new" (i.e. post July 1, 1994) and reported in keeping with the requirements for non-transitional substances. CEPA, 1999, is very clear on this point. Subsection 81(2) deals specifically with substances manufactured or imported during the transitional period. Biochemicals addressed under this subsection are specifically excluded from consideration under subsection 81(1) which deals with all other substances subject to notification. These two subsections of the Act are seen as being mutually exclusive, thereby precluding any option in determining the appropriate regulatory track. Any biochemical manufactured or imported in excess of 20 kg/yr in the transitional period must be notified in accordance with the Regulatory requirements applicable to subsection 81(2).

It is important to emphasize that notification is not required for a transitional substance if manufacture or import was terminated on or before June 30, 1994. In such situations the company would be in compliance with the requirements of subsection 81(2) to "not manufacture or import the substance".

2.6 Notification of biochemicals or biopolymers first manufactured or imported between July 1, 1994 and September 1, 1997

Under subsections 81(1) and 81(2) of the CEPA, 1999 the manufacture or importation of a substance is prohibited unless the prescribed information has been provided and the period for assessing the information has expired. Accordingly, for a biochemical or a biopolymer first manufactured or imported between July 1, 1994 and September 1, 1997, a notification must have been provided before September 1, 1997. This is required in order that the manufacture or importation of the biochemical or biopolymer continues, subject to the results of the assessment, after September 1, 1997.

A six month period of time between the date of publication of the Biotechnology portion of the NSNR in the *Canada Gazette*, Part II (March 1997) and the date on which that portion came into force (September 1, 1997) was provided to allow for the preparation, submission and assessment of notifications prior to September 1, 1997.

If these biochemicals and biopolymers were not notified and assessed before September 1, 1997, their manufacture or importation had to cease on September 1, 1997 until a notification is provided and the assessment period has expired.

Section 3 - Information Requirements

Subsections 81(1) and 81(2) of CEPA, 1999 prohibit the import or manufacture of any substance not listed on the DSL Subsections 81(1) and 81(2) of CEPA, 1999 prohibit the import or manufacture of any substance not listed on the DSL Subsections 81(1) and 81(2) of CEPA, 1999 prohibit the import or manufacture of any substance not listed on the DSL Subsections 81(1) and 81(2) of CEPA, 1999 prohibit the import or manufacture of any substance not listed on the DSL unless the prescribed information is provided within the prescribed time, and the period for assessing the information has expired. The prescribed information specified in the New Substances Notification Regulations (Appendix 1) consists of both technical and administrative information (described in Sections 4 and 8, respectively).

The New Substances Notification Regulations provide a tiered approach to notification that links information requirements to factors such as quantity, use, intrinsic properties, and class. This section will help identify both the technical information necessary to comply with the NSNR and the date before which notifications must be submitted to Environment Canada.

3.1 Classification of Substances

For the purposes of the New Substances Notification Regulations, new substances are grouped into three major classes, each subject to its own specific information requirements. These classes are non-polymeric chemicals (referred to in these Guidelines as chemicals), polymers, and products of biotechnology. Products of biotechnology are further grouped into two classes, namely animate products of biotechnology (i.e. living organisms) and inanimate products of biotechnology (i.e. biochemicals and biopolymers).

3.1.1 Chemicals and biochemicals

The information requirements for chemicals and biochemicals (substances produced by micro-organisms) are prescribed in Part I of the NSNR and apply to all substances that are neither polymers nor animate products of biotechnology. Note that products of biotechnology derived from a whole plant or animal or from parts of a whole plant or animal are considered chemicals or polymers rather than biochemicals or biopolymers. Cell cultures are not considered to be part of a whole plant or animal; therefore, products derived from cell cultures are subject to the Biotechnology portion of the NSNR.

3.1.2 Polymers and biopolymers

The information requirements for polymers and biopolymers (substances produced by micro-organisms) are prescribed in Part II of the Regulations and apply to substances consisting of:

(a) molecules characterized by the sequence of one or more types of monomer units;

(b) a simple weight majority (>50% by weight) of molecules containing at least three monomer units covalently bound to at least one other monomer unit or reactant;

(c) less than a simple weight majority of molecules of the same molecular weight; and

(d) molecules distributed over a range of molecular weights, and differences in the molecular weights are primarily attributable to differences in the number of monomer units.

For biopolymers, monomer units and reactants are considered to be the repeating units within the polymeric substance which are either produced *in situ* by the micro-organism, or are added to the reaction vessel.

Part II of the NSNR does not apply to animate products of biotechnology. Note that products of biotechnology derived from a whole plant or animal or from parts of a whole plant or animal are considered chemicals or polymers rather than biochemicals or biopolymers. Cell cultures are not considered to be part of a whole plant or animal; therefore, products derived from cell cultures are subject to the Biotechnology portion of the NSNR.

A polymer or biopolymer manufactured by modifying the formulation of a polymer or biopolymer specified on the DSL by adding reactants, none of which constitutes more than two percent by weight of the polymer or biopolymer, is exempt from notification. Note that the term modifying refers to the amount of additional reactant that has been incorporated into the structure of the polymer or the amount charged to the vessel.

3.1.3 Products of Biotechnology

The Biotechnology portion of the New Substances Notification Regulations, implemented on September 1, 1997, addresses micro-organisms, parts of micro-organisms, organisms other than micro-organisms, and substances produced by micro-organisms. The provisions under the NSNR for biochemicals and biopolymers build on the provisions for chemicals and polymers. The Biotechnology portion of the NSNR was published in the Canada Gazette, Part II, on March 5, 1997.

3.2 How to Identify the Required Notification Information

These guidelines deal only with information requirements of the chemical/biochemical and polymer/biopolymer portions of the NSNR.

3.2.1 *Chemicals and biochemicals*

The New Substances Notification Regulations prescribe information requirements tailored to the use and quantity of the chemical or biochemical. These requirements are specified in the Schedules in Appendix 1. Decision flowcharts are provided in Subsection 3.2.1.2 to help select the appropriate Schedule.

Before using the flowcharts, Subsections 3.2 to 3.7 should be reviewed to determine:

(a) whether the chemical/biochemical is listed in the Non-domestic Substances List (NDSL);

(b) whether the chemical/biochemical meets the criteria for a transitional substance;

(c) whether the chemical/biochemical falls within any of the prescribed special categories; and

(d) an estimate of the yearly and cumulative manufacture or import quantities.

3.2.1.1 *Special Categories of Chemicals/Biochemicals*

Research and Development. Research and development chemicals/biochemicals are chemicals/biochemicals that are the subject of systematic investigation or search (by means of experimentation or analysis, or both) that has as its primary objective the creation or improvement of a product. This category includes chemicals/biochemicals being manufactured on toll for domestic or foreign customers that are conducting research.

Product Development. Product development chemicals/biochemicals are research and development chemicals/biochemicals evaluated before full commercialization using pilot plants, production trials, or customer trials in one program that is two years or less in length. The intent of this activity is to modify technical specifications in response to performance requirements of potential customers; however, test marketing is not included. This category includes chemicals/biochemicals being manufactured on toll for domestic or foreign customers that are conducting research.

Export Only. This category is limited to chemicals/biochemicals imported into, or manufactured in, Canada and destined solely for foreign markets.

Site-limited Intermediates. An intermediate chemical/biochemical is a chemical/biochemical that is consumed, in whole or in part, in a chemical reaction used for the intentional manufacture of another substance. A site-limited intermediate is defined in the Regulations as an intermediate:

(a) not exceeding an accumulated quantity of 50 000 kg; and

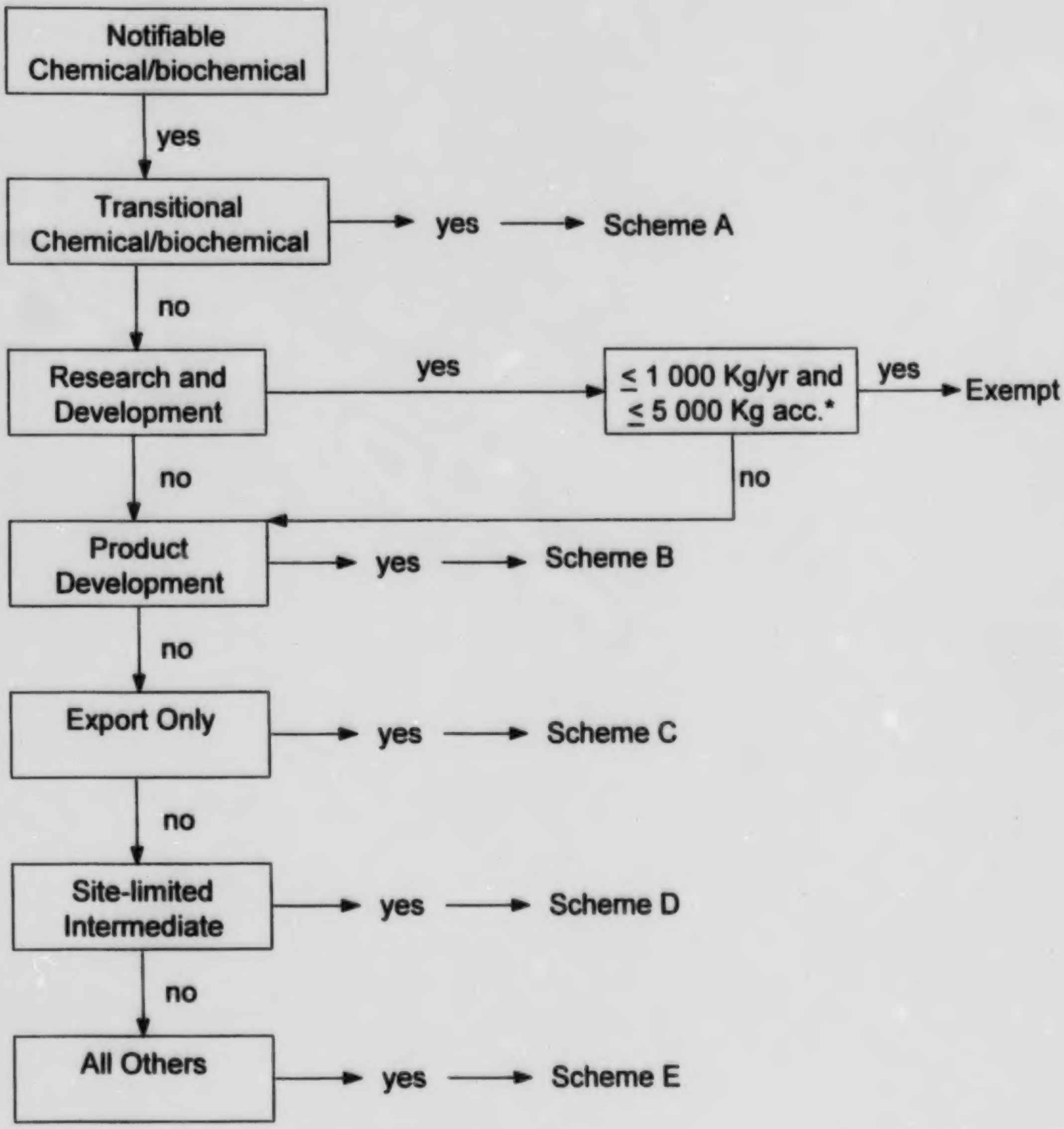
(b) at any one time, the combined inventory of the chemical/biochemical:
(1) manufactured for the purpose of being consumed on the site of manufacture;
(2) manufactured at one site in Canada and then transported to a second site in Canada where it is consumed; or
(3) imported and transported directly to one site where it is consumed, does not exceed 10 000 kg.

"Consumed" in this case implies that the reaction has proceeded to the point where no further conversion of the substance is likely under the reaction conditions, i.e., some of the site-limited substance may remain as a minor impurity in the final product.

If a substance is classified as a site-limited intermediate, it must at all times during its existence (manufacture, storage, transport, handling, use, and disposal), be adequately contained to prevent any significant environmental release.

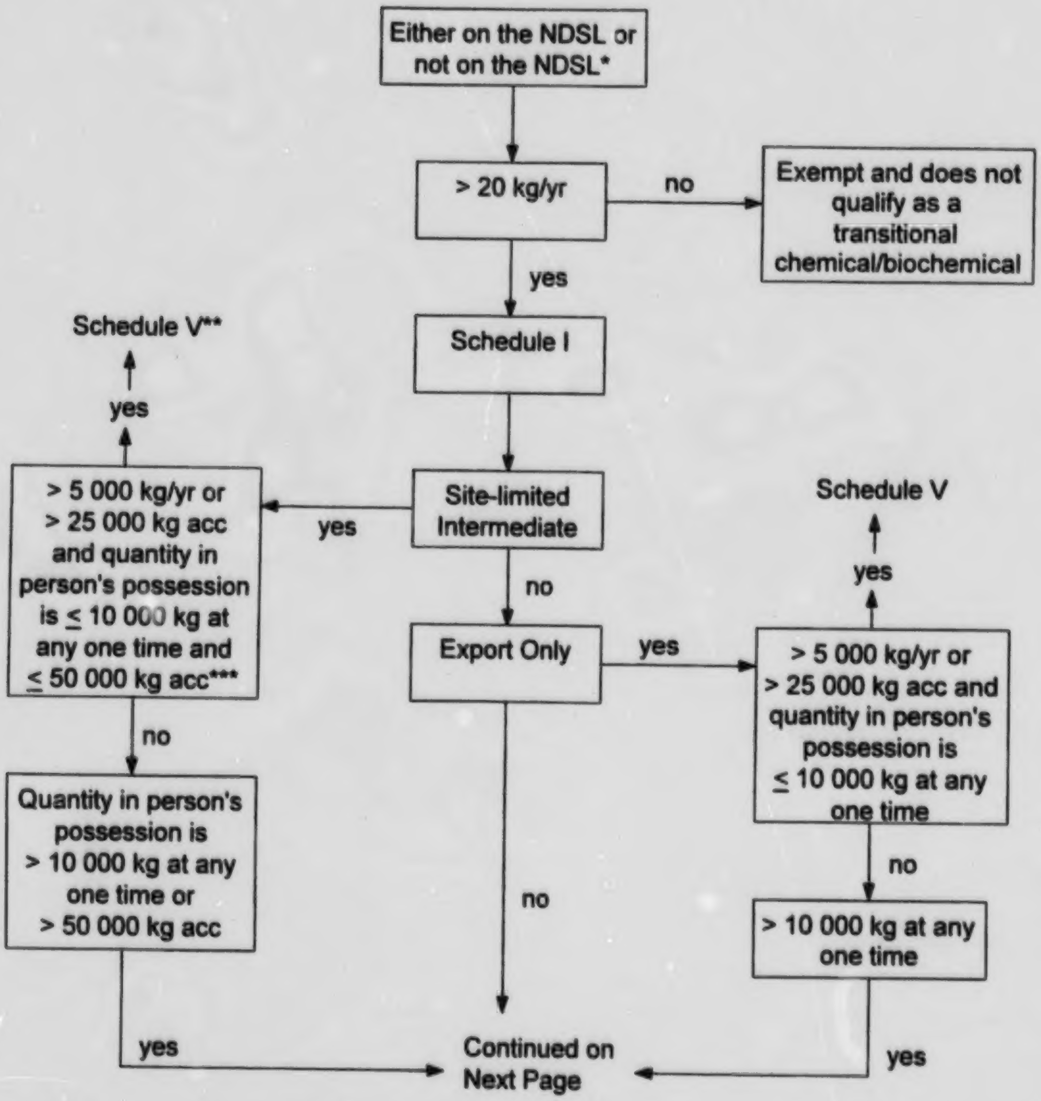
Chemicals/biochemicals that are a direct precursor in the manufacture of an item defined in Subsection 2.4.1.2 of these Guidelines are not considered site-limited intermediates, and would be subject to the regular notification requirements. However, if the direct precursor of the item meets the criteria of a "transient reaction intermediate" (Subsection 2.4.2.2), it would not be subject to notification.

3.2.1.2 Decision Schemes. The decision schemes shown in Figures 1 to 6 can be used to determine the required schedule of information for chemicals and biochemicals. The dates before which the information requirements must be provided are given in Subsection 3.6 of these Guidelines.


Notifiable Chemical/biochemical
yes
Transitional Chemical/biochemical
yes
Scheme A
no
Research and Development
yes
≤ 1 000 Kg/yr and ≤ 5 000 Kg acc.*
yes
Exempt
no
no
Product Development
yes
Scheme B
no
Export Only
yes
Scheme C
no
Site-limited Intermediate
yes
Scheme D
no
All Others
yes
Scheme E

* acc = accumulated total

Figure 1 **Notification Requirements for New Chemicals/biochemicals***
*** for biochemicals, additional requirements set out in Schedule XIV must also be provided**


Either on the NDSL or not on the NDSL*
> 20 kg/yr
no
Exempt and does not qualify as a transitional chemical/biochemical
yes
Schedule I
Schedule V**
yes
Site-limited Intermediate
yes
> 5 000 kg/yr or > 25 000 kg acc and quantity in person's possession is ≤ 10 000 kg at any one time and ≤ 50 000 kg acc***
no
Quantity in person's possession is > 10 000 kg at any one time or > 50 000 kg acc
yes
no
Export Only
yes
Schedule V
yes
> 5 000 kg/yr or > 25 000 kg acc and quantity in person's possession is ≤ 10 000 kg at any one time
no
> 10 000 kg at any one time
yes
no
Continued on Next Page

* When notification of the most comprehensive transitional information package (i.e., Schedule II for chemicals) is received during the five-year post-transitional period, no additional notification obligations will be imposed even if a non-NDSL substance exceeds a Schedule III trigger quantity after the five-year period expires.
**Site-limited intermediates that are not transported off-site are exempt from hydrolysis, ready biodegradability, and acute mammalian toxicity requirements (items 3 and 4 of Schedule V).
***acc = accumulated total.

Figure 2 **Scheme A: Transitional Chemicals/biochemicals***
*** for biochemicals, additional requirements set out in Schedule XIV must also be provided** XE "chemicals:determining information requirements"

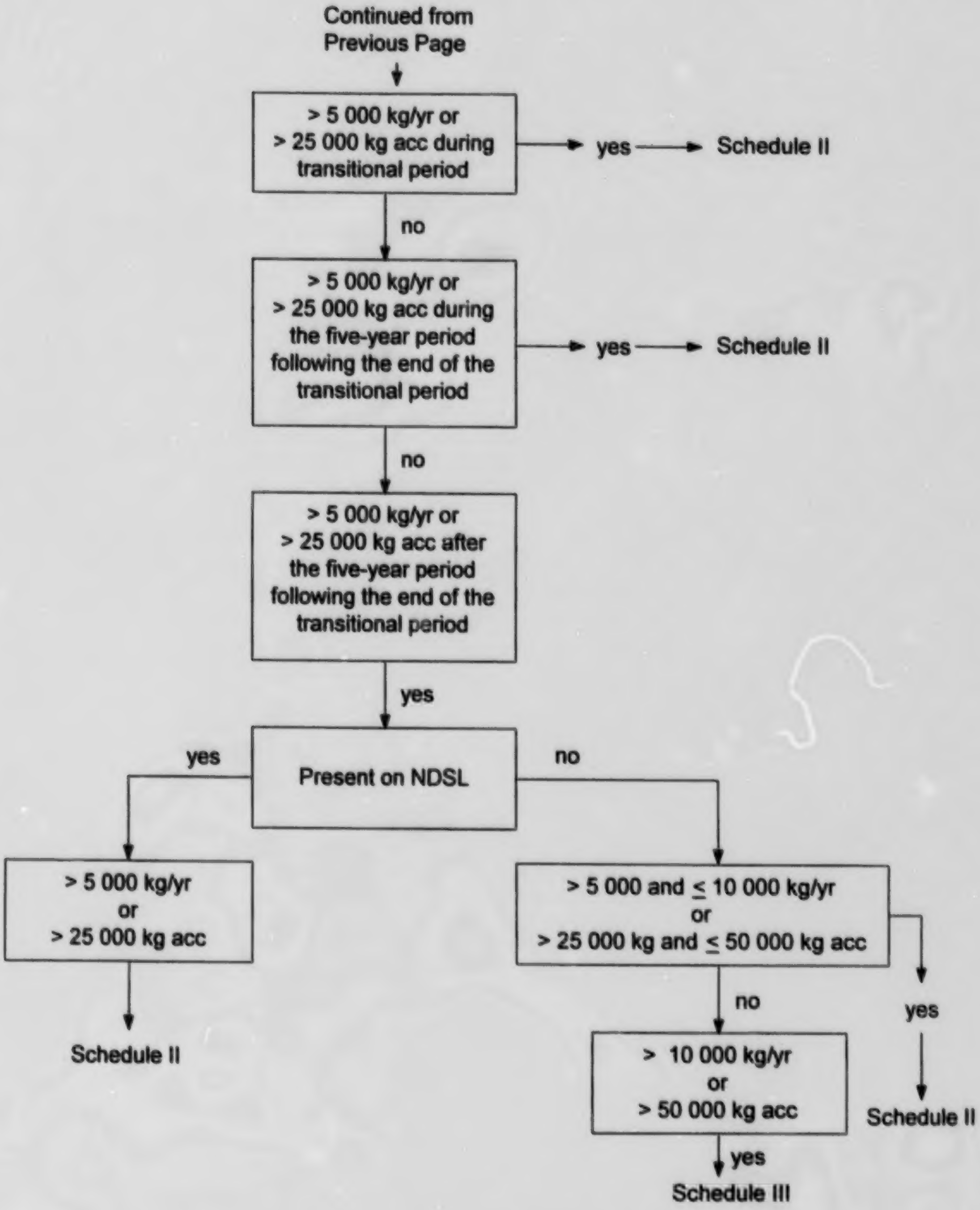
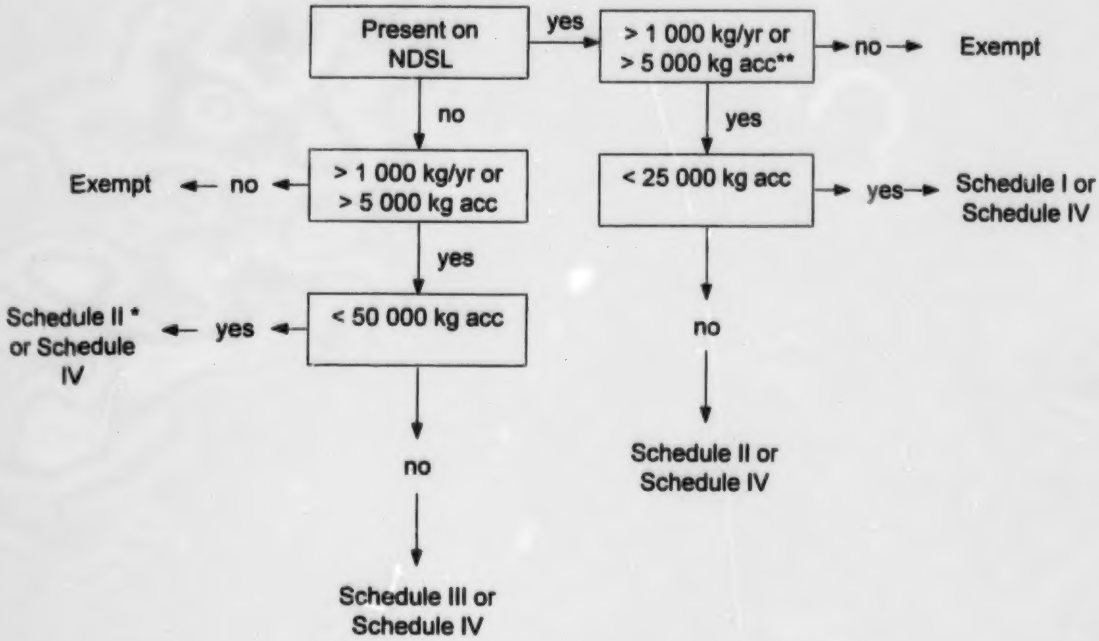
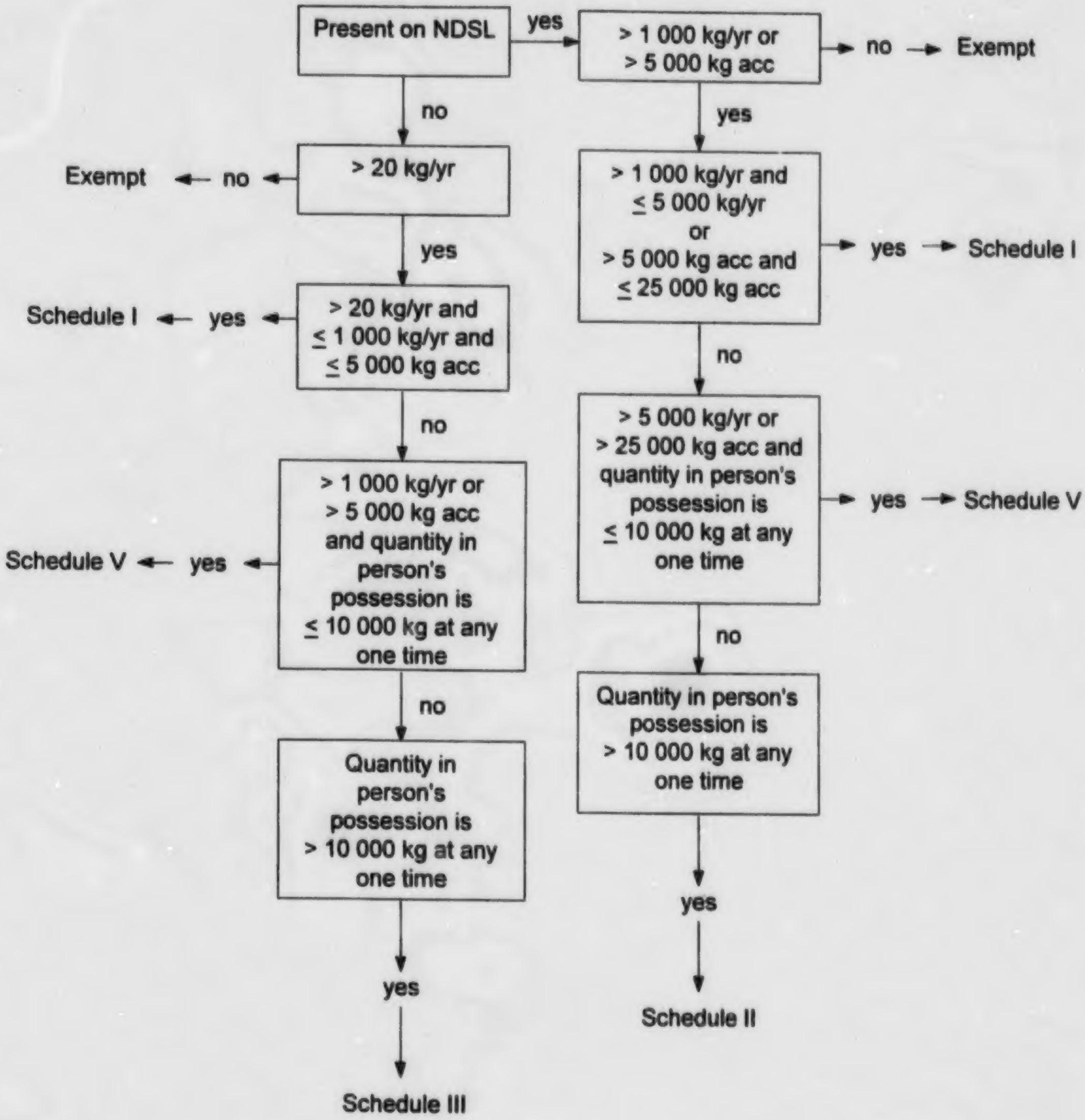

Continued from Previous Page
> 5 000 kg/yr or > 25 000 kg acc during transitional period
yes
Schedule II
no
> 5 000 kg/yr or > 25 000 kg acc during the five-year period following the end of the transitional period
yes
Schedule II
no
> 5 000 kg/yr or > 25 000 kg acc after the five-year period following the end of the transitional period
yes
Present on NDSL
yes
no
> 5 000 kg/yr or > 25 000 kg acc
Schedule II
> 5 000 and ≤ 10 000 kg/yr or > 25 000 kg and ≤ 50 000 kg acc
no
yes
> 10 000 kg/yr or > 50 000 kg acc
Schedule II
yes
Schedule III

Figure 2 **Scheme A: Transitional Chemicals/biochemicals* (*continued*)**
*** for biochemicals, additional requirements set out in Schedule XIV must also be provided** XE "chemicals:determining information requirements"


Present on NDSL
yes
> 1 000 kg/yr or > 5 000 kg acc**
no
Exempt
no
yes
Exempt
no
> 1 000 kg/yr or > 5 000 kg acc
< 25 000 kg acc
yes
Schedule I or Schedule IV
yes
Schedule II * or Schedule IV
yes
< 50 000 kg acc
no
Schedule II or Schedule IV
no
Schedule III or Schedule IV

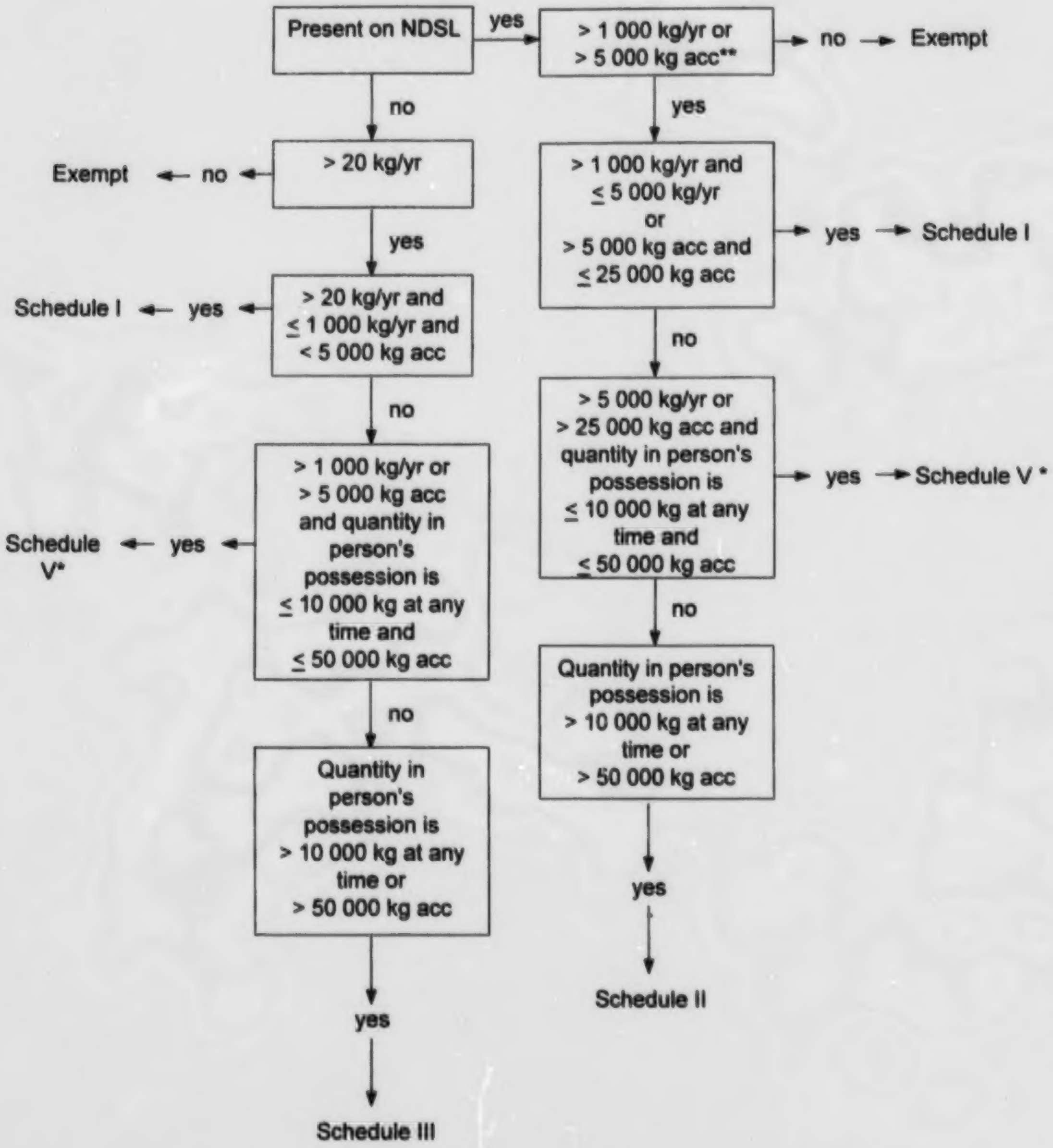
*Except for adsorption-desorption screening test data and hydrolysis as a function of pH test data (items 2(1)(i) and 2(1)(j) of Schedule II).
**acc = accumulated total

Figure 3 **Scheme B: Product Development Chemicals/biochemicals***
*** for biochemicals, additional requirements set out in Schedule XIV must also be provided** XE "chemicals:determining information requirements"


Present on NDSL
yes
> 1 000 kg/yr or > 5 000 kg acc
no
Exempt
yes
> 1 000 kg/yr and ≤ 5 000 kg/yr or > 5 000 kg acc and ≤ 25 000 kg acc
yes
Schedule I
no
> 5 000 kg/yr or > 25 000 kg acc and quantity in person's possession is ≤ 10 000 kg at any one time
yes
Schedule V
no
Quantity in person's possession is > 10 000 kg at any one time
yes
Schedule II
no
> 20 kg/yr
no
Exempt
yes
> 20 kg/yr and ≤ 1 000 kg/yr and ≤ 5 000 kg acc
yes
Schedule I
no
> 1 000 kg/yr or > 5 000 kg acc and quantity in person's possession is ≤ 10 000 kg at any one time
yes
Schedule V
no
Quantity in person's possession is > 10 000 kg at any one time
yes
Schedule III

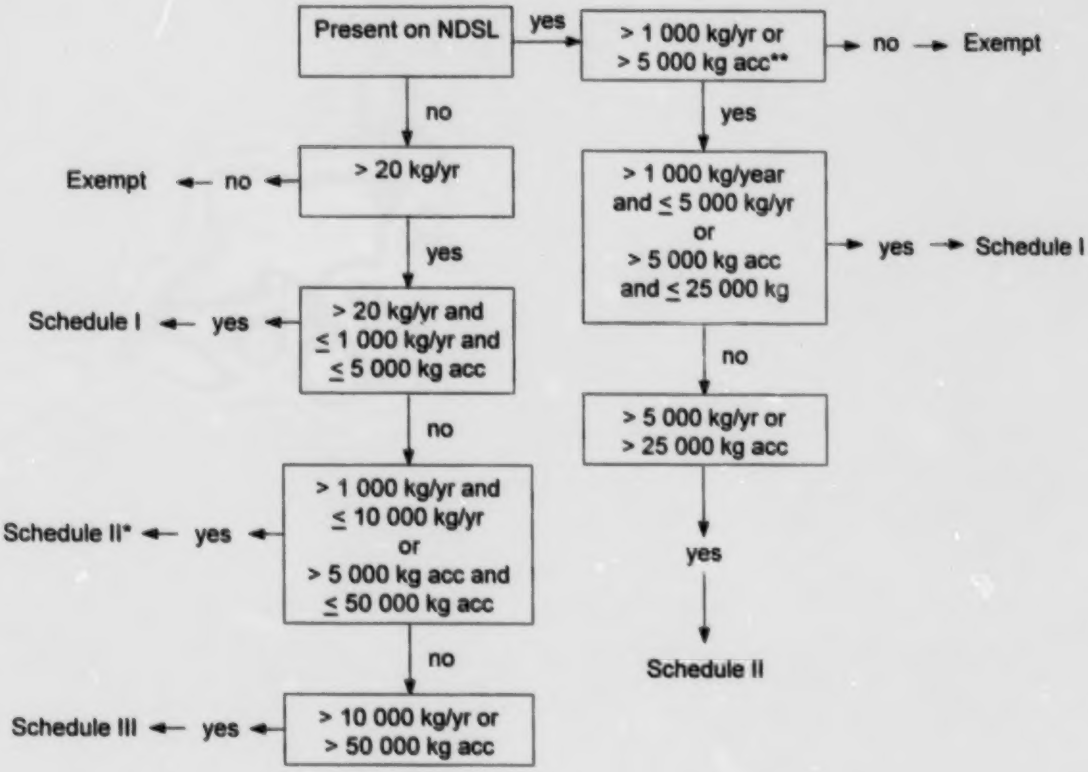
*acc = accumulated total

Figure 4 **Scheme C: Export only Chemicals/biochemicals***
*** for biochemicals, additional requirements set out in Schedule XIV must also be provided** XE "chemicals:determining information requirements"


Present on NDSL
yes
> 1 000 kg/yr or > 5 000 kg acc**
no
Exempt
no
yes
> 20 kg/yr
Exempt
no
yes
> 1 000 kg/yr and ≤ 5 000 kg/yr or > 5 000 kg acc and ≤ 25 000 kg acc
yes
Schedule I
> 20 kg/yr and ≤ 1 000 kg/yr and < 5 000 kg acc
Schedule I
yes
no
no
> 5 000 kg/yr or > 25 000 kg acc and quantity in person's possession is ≤ 10 000 kg at any time and ≤ 50 000 kg acc
yes
Schedule V *
> 1 000 kg/yr or > 5 000 kg acc and quantity in person's possession is ≤ 10 000 kg at any time and ≤ 50 000 kg acc
Schedule V*
yes
no
no
Quantity in person's possession is > 10 000 kg at any time or > 50 000 kg acc
Quantity in person's possession is > 10 000 kg at any time or > 50 000 kg acc
yes
Schedule II
yes
Schedule III

*Site-limited intermediates that are not transported off-site are exempt from hydrolysis, ready biodegradability, and acute mammalian toxicity requirements (items 3 and 4 of Schedule V).
**acc = accumulated total

Figure 5 **Scheme D: Site-limited Intermediate Chemicals/biochemicals***
*** for biochemicals, additional requirements set out in Schedule XIV must also be provided XE "chemicals:determining information requirements"**


Present on NDSL
yes
> 1 000 kg/yr or
> 5 000 kg acc**
no
Exempt
no
yes
Exempt
no
> 20 kg/yr
> 1 000 kg/year
and ≤ 5 000 kg/yr
or
> 5 000 kg acc
and ≤ 25 000 kg
yes
Schedule I
yes
Schedule I
yes
> 20 kg/yr and
≤ 1 000 kg/yr and
≤ 5 000 kg acc
no
no
> 5 000 kg/yr or
> 25 000 kg acc
> 1 000 kg/yr and
≤ 10 000 kg/yr
or
> 5 000 kg acc and
≤ 50 000 kg acc
Schedule II*
yes
yes
Schedule II
no
Schedule III
yes
> 10 000 kg/yr or
> 50 000 kg acc

*Except for adsorption-desorption screening test data and hydrolysis as a function of pH test data (subitems 2(1)(i) and 2(1)(j) of Schedule II).
**acc = accumulated total

Figure 6 **Scheme E: All Other Chemicals/biochemicals***
*** for biochemicals, additional requirements set out in Schedule XIV must also be provided** XE "chemicals:determining information requirements"

3.2.2 Polymers and Biopolymers

The New Substances Notification Regulations prescribe information requirements tailored to the type, use, and quantity of the polymer/biopolymer. These requirements are specified in Schedules found in Appendix 1. A decision flowchart is provided in Subsection 3.2.2.4 to help select the appropriate schedule. Before using the flowchart, Subsections 3.2. to 3.7 should be reviewed to determine:

(a) whether the substance meets the definition of a polymer/biopolymer given in the Regulations ,

(b) whether the polymer/biopolymer meets the criteria for a transitional substance;

(c) whether the polymer/biopolymer is listed on the NDSL;

(d) whether or not each monomer and reactant appears on the NDSL or the DSL;

(e) whether the polymer/biopolymer meets the criteria for a low-concern polymer/biopolymer;

(f) whether the polymer/biopolymer falls within any of the prescribed special categories; and

(g) an estimate of the yearly and cumulative manufacture or import quantities.

3.2.2.1 Monomers and Reactants on the Non-domestic Substances List and the Domestic Substances List. To determine whether a polymer/biopolymer notification is eligible for reduced information requirements, it is necessary to find out if the monomers and reactants of the substance appear on the DSL or NDSL.

3.2.2.2 Low-concern Polymers/biopolymers. Low-concern polymers/biopolymers include polymers/biopolymers of high number-average molecular weight that have a limited percentage of low molecular weight components and that are chemically stable and do not contain certain reactive or cationic moieties.

Low-concern polymers/biopolymers include those polymers/biopolymers that:

(a) are not described in items 1, 2, 3, or 4 of Schedule IX and have a number-average molecular weight greater than 10 000 daltons, and less than 2% of components have a molecular weight less than 500 daltons, and less than 5% of components have a molecular weight less than 1 000 daltons;

(b) are not described in Schedule IX and have a number-average molecular weight greater than 1 000 daltons, and less than 10% of components have a molecular weight less than 500 daltons, and less than 25% of components have a molecular weight less than 1 000 daltons; or

(c) are polyesters manufactured solely from reactants listed in Schedule X, or an anhydrous form of those reactants, other than the reactants or the anhydrous forms of these reactants that include both 1-butanol and 2-butenedioic acid (*E*).

Polymers Described in Schedule IX. Schedule IX of the NSNR outlines some of the criteria used to determine whether a polymer is of low concern. In particular, items 1 and 5 of Schedule IX describe circumstances where cationic or reactive polymers fail to meet low concern criteria. Part of this determination involves calculating the functional group equivalent weight (FGEW) of resident cationic or reactive functional groups. Procedures for performing these calculations are described below.

Item 1

Item 1 of Schedule IX indicates that a polymer meets one of the low concern criteria if it "has a combined functional group equivalent weight for the cationic group greater than 5000". The phrase "functional group equivalent weight for the cationic groups" (also referred to as FGEW) is the ratio of the mass of the polymer to the number of moles of the cationic group. Consequently, larger FGEW values represent polymers that have relatively few cationic species.

The FGEW of a cationic group is equal to:

$$\frac{\textit{(molecular weight of the monomer)} \times 100}{\textit{(number of groups in the monomer) (percent by weight of the monomer)}}$$

The following three examples demonstrate how the equation should be used to determine the FGEW.

Example 1: A cationic polymer contains ammonium ions that are derived solely from the monomer 3-aminopropionic acid ($NH_2CH_2CH_2COOH$, molecular weight 89.1), which accounts for 30 percent by weight of the polymer. Therefore:

$$\text{FGEW} = \frac{(89.1) \times (100)}{(1) \times (30)}$$

which equals 297 g of polymer per mole of cationic group. Because this value is less than 5000, this polymer would not be of low concern based on this criterion.

Example 2: A cationic polymer contains ammonium ions that are derived solely from the monomer 2,3-diaminopropionic acid ($NH_2CH_2CH(NH_2)COOH$, molecular weight 104.11), which accounts for 1 percent by weight of the polymer. Therefore:

$$\text{FGEW} = \frac{(104.11) \times (100)}{(2) \times (1)}$$

which equals 5205.5 g of polymer per mole of cationic group. This value is greater than 5000; therefore, the polymer meets this criterion for low concern.

If the cationic group in the polymer originates from more than one monomer, the FGEW must be calculated for each monomer. The combined FGEW is calculated as:

$$\text{FGEW}_{\text{comb}} = \frac{1}{1/\text{FGEW}_1 + 1/\text{FGEW}_2 + \ldots + 1/\text{FGEW}_n}$$

Example 3: If a polymer contained the same percentage weights of both of the cationic groups in Examples 1 and 2, then:

$$\text{FGEW}_{\text{comb}} = \frac{1}{1/297 + 1/5205.5}$$

which equals approximately 281 g of polymer per mole of cationic group. Because this value is less than 5000, the polymer would not be of low concern based on this criterion.

Item 4

A polymer that contains:

(a) any atomic elements other than carbon, hydrogen, nitrogen, oxygen, silicon, sulphur, fluorine, chlorine, bromine or iodine covalently bound to carbon;
(b) any monoatomic counterions other than chlorine ion, bromine ion, iodine ion, sodium ion, divalent magnesium, trivalent aluminum, potassium ion or divalent calcium; and
(c) 0.2% or more by weight of any atomic element or combination of the following atomic elements: lithium, boron, phophorus, titanium, manganese, iron, nickel, copper, zinc, tin or zirconium.

Item 5

A Polymer

(a) that contain reactive functional groups other than: carboxylic acid groups, aliphatic hydroxyl groups, unconjugated olefinic groups that are considered "ordinary"*, butenedioic acid groups, blocked isocyanates including ketoxime-blocked isocyanates, thiols, unconjugated nitrile groups, halogens excluding reactive halogen-containing groups such as benzylic or allylic halides, and conjugated olefinic groups contained in naturally occurring fats, oils, and carboxylic acids, in combined equivalent weight of less than a FGEW of 5000;

(b) in which the only reactive functional groups present are part of acids halides, acid anhydrides, aldehydes, hemiacetals, methylol-amides, methylol-amines, methylol-ureas, alkoxysilanes with alkoxy greater than C_2-alkoxysilanes, allyl ethers, conjugated olefins, cyanates, epoxides, imines, unsubstituted positions ortho or para to phenolic hydroxyl, in combined equivalent weights of less than a FGEW of 1000.

* not specially activated either by being part of a larger functional group, such as a vinyl ether, or by other activating influences, for example, strongly electron-withdrawing sulfone group with which the olefinic groups interact.

Example 4: A polymer contains 3% by weight of acryloyl chloride ($H_2C{=}CH(COCl)$, molecular weight 90.5).

First, determine whether the reactive functional group is included in part (a) or part (b) of item 5. Acid halides are included under part (b); therefore, FGEW $\leq$ 1000 is used to determine the level of concern. The FGEW of the acid chloride equals:

$$\text{FGEW} = \frac{90.5 \times 100}{1 \times 3} = 3017$$

Because this FGEW is greater than 1000, the polymer is of low concern according to this criterion.

Example 5: A polymer contains pendant acrylates. This polymer is included in part (a) of item 5, therefore, FGEW $\leq$ 5000 is used to determine the level of concern. Assume a calculation similar to the one in Example 4 results in a FGEW of 4400. Because this FGEW is less than 5000, the polymer is not of low concern according to this criterion.

Example 6: If the reactive functional groups in the previous two examples were included in a single polymer, their FGEW's would have to be combined and compared to the standard of $\text{FGEW}_{comb} \leq 5000$ to determine the level of concern.

$$\text{FGEW}_{comb} = \frac{1}{1/3017 + 1/4400} = 1790$$

Because this $FGEW_{comb}$ is less than 5000, the polymer is not of low concern according to this criterion.

To simplify matters, Environment Canada is providing the following table of FGEW values.

Table of Molecular Weight of the Monomer versus the Percent by Weight of the Monomer

	50	75	100	125	150	175	200	225	250	275	300
2%	2500	3750	5000	6250	7500	8750	10000	11250	12500	13750	15000
5%	1000	1500	2000	2500	3000	3500	4000	4500	5000	5500	6000
10%	500	750	1000	1250	1500	1750	2000	2250	2500	2750	3000
15%	333	500	667	833	1000	1167	1333	1500	1667	1833	2000
20%	250	375	500	625	750	875	1000	1125	1250	1375	1500
25%	200	300	400	500	600	700	800	900	1000	1100	1200
30%	167	250	333	417	500	583	667	750	833	917	1000

3.2.2.3 Special Categories of Polymers/Biopolymers

Research and Development. Research and development polymers/biopolymers are polymers/biopolymers that are the subject of systematic investigation or search (by means of experimentation or analysis, or both) that has as its primary objective the creation or improvement of a product. This category includes polymers/biopolymers being manufactured on toll for domestic or foreign customers that are conducting research.

Product Development Polymers/Biopolymers. Product development polymers/biopolymers are research and development polymers/biopolymers evaluated before full commercialization using pilot plants, production trials, or customer trials in one program that is two years or less in length. The intent of this activity is to modify technical specifications in response to performance requirements of potential customers; however, test marketing is not included. This category includes polymers/biopolymers being manufactured on toll for domestic or foreign customers that are conducting research.

Export Only. This category includes polymers/biopolymers imported into, or manufactured in, Canada and destined solely for foreign markets.

Site-limited Intermediates. An intermediate substance is a substance that is consumed, in whole or in part, in a chemical reaction used for the intentional manufacture of another substance. A site-limited intermediate polymer/biopolymer is defined in the Regulations as an intermediate:

(a) not exceeding an accumulated quantity of 50 000 kg; and

(b) at any one time, the combined inventory of the polymer/biopolymer:

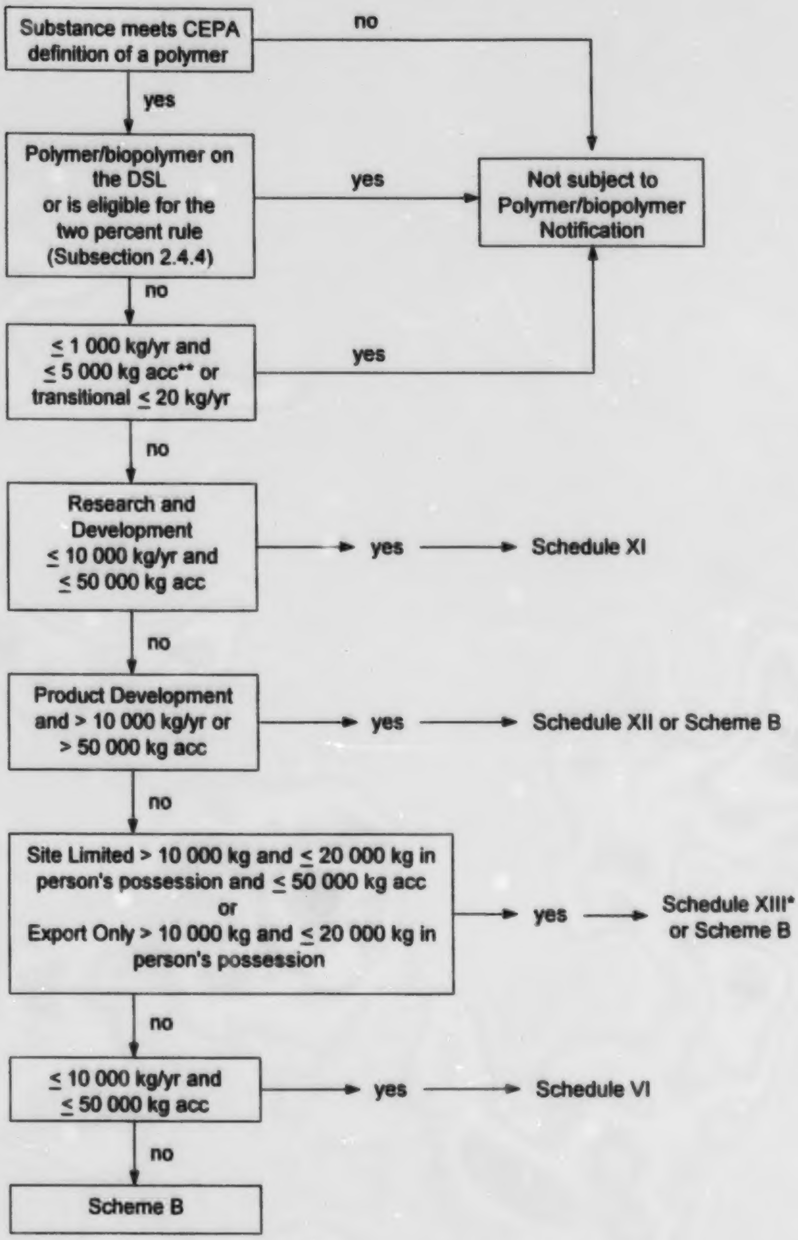
(1) manufactured for the purpose of being consumed on the site of manufacture;
(2) manufactured at one site in Canada and then transported to a second site in Canada where it is consumed; or
(3) imported and transported directly to one site at which it is consumed does not exceed 20 000 kg.

"Consumed" in this case implies that the reaction has proceeded to the point where no further conversion of the substance is likely under the reaction conditions, i.e., some of the site-limited substance may remain as a minor impurity in the final product.

If a substance is classified as a site-limited intermediate, it must at all times during its existence (manufacture, storage, transport, handling, use, and disposal) be adequately contained to prevent any significant environmental release.

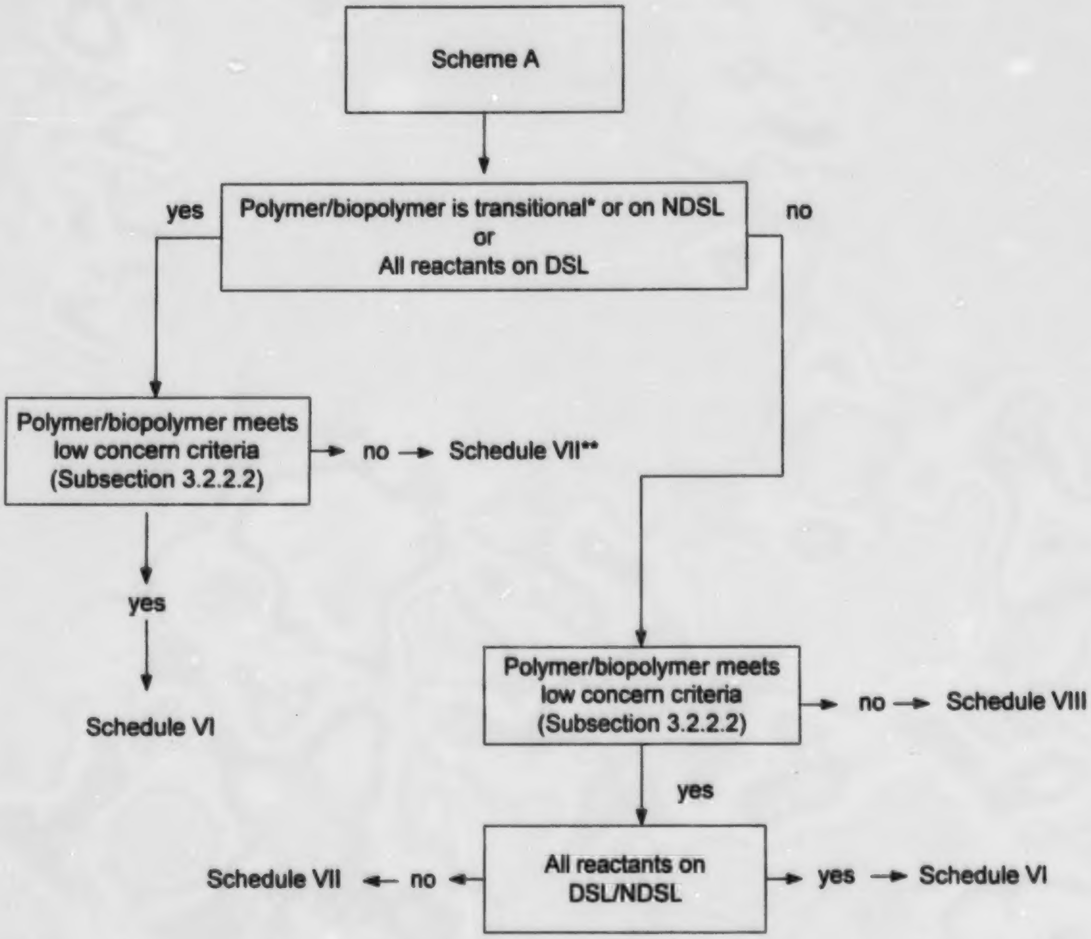
Polymers/biopolymers that are a direct precursor in the manufacture of an item defined in Subsection 2.4.1.2 of these Guidelines are not considered site-limited intermediates, and would be subject to the regular notification requirements. However, if the direct precursor of the item meets the criteria of a "transient reaction intermediate" (Subsection 2.4.2.2), it would not be subject to notification.

3.2.2.4 ***Decision Schemes.*** The decision schemes shown in Figures 7 and 8 can be used to determine the required schedule of information for polymers and biopolymers. The dates before which the information requirements must be provided are given in Subsection 3.6 of these Guidelines.


Substance meets CEPA definition of a polymer
no
yes
Polymer/biopolymer on the DSL or is eligible for the two percent rule (Subsection 2.4.4)
yes
Not subject to Polymer/biopolymer Notification
no
≤ 1 000 kg/yr and ≤ 5 000 kg acc** or transitional ≤ 20 kg/yr
yes
no
Research and Development ≤ 10 000 kg/yr and ≤ 50 000 kg acc
yes
Schedule XI
no
Product Development and > 10 000 kg/yr or > 50 000 kg acc
yes
Schedule XII or Scheme B
no
Site Limited > 10 000 kg and ≤ 20 000 kg in person's possession and ≤ 50 000 kg acc or Export Only > 10 000 kg and ≤ 20 000 kg in person's possession
yes
Schedule XIII* or Scheme B
no
≤ 10 000 kg/yr and ≤ 50 000 kg acc
yes
Schedule VI
no
Scheme B

*Site-limited intermediates that are not transported off-site are exempt from molecular and structural formulae, number average molecular weight, percentage residual constituents, water solubility, octanol solubility, and acute mammalian toxicity information requirements (items 1(4), 1(5), 2 and 3 of Schedule XIII).
**acc = accumulated total.

Figure 7 **Notification Requirements for New Polymers/biopolymers*: Scheme A**
*** for biopolymers, additional requirements set out in Schedule XIV must also be provided**


Scheme A
yes
Polymer/biopolymer is transitional* or on NDSL
or
All reactants on DSL
no
Polymer/biopolymer meets low concern criteria (Subsection 3.2.2.2)
no
Schedule VII**
yes
Schedule VI
Polymer/biopolymer meets low concern criteria (Subsection 3.2.2.2)
no
Schedule VIII
yes
All reactants on DSL/NDSL
Schedule VII
no
yes
Schedule VI

*The provisions for transitional substances expire five years after the New Substances Notification Regulations come into force. When the most comprehensive information package is received during the five-year post-transitional period, no additional notification obligations will be imposed after the five-year period expires.
**Acute fish or *Daphnia* toxicity [subitem 2(2)] not required for NDSL polymers/biopolymers.

Figure 8 Notification Requirements for New Polymers/biopolymers*: Scheme B
*** for biopolymers, additional requirements set out in Schedule XIV must also be provided**

3.3 Substances on the Non-domestic Substances List

The Non-domestic Substances List (NDSL) specifies substances that are not on the DSL but are in commercial use in the United States. As a basis for this list, Environment Canada used the United States *Toxic Substances Control Act* (TSCA) Inventory of 1985, which lists more than 58 000 substances. The NDSL, published on January 26, 1991, consisted of the 1985 version of the TSCA list minus the substances on the DSL. Substances listed on the NDSL require less detailed notification packages for assessment than substances that are new to both the Canadian marketplace and world commerce.

The NDSL also contains a listing of confidential substances that originated from the confidential part of the TSCA inventory. These substances were listed on the confidential NDSL only if the nominating company could demonstrate that the substance existed on the confidential TSCA inventory. Procedures for determining the presence of confidential substances on the NDSL and the DSL are described in Section 9.3 of these Guidelines.

Updates to the NDSL. Beginning in 1995, the NDSL has undergone annual revisions that have added or deleted all substances incorporated into, or removed from, the TSCA inventory five or more years before the date of the NDSL revision. The first NDSL update therefore included substances in the 1990 supplement of the TSCA inventory. Substances on the TSCA inventory that have restrictions imposed on their manufacture or import as a result of a risk assessment by the U.S. EPA are not being added to the NDSL.

Substances can be listed on the confidential NDSL only if the nominating company demonstrates that the substance exists on the confidential TSCA inventory and is not listed on any other public chemical Inventory such as AICS (Australian Inventory), ECL (Korean Inventory), EINECS (European Inventory) and ENCS (Japanese Inventory). Instructions for nominating substances to the confidential NDSL are on the back of the Domestic Substances List Report Form C, which can be obtained through the NSN Information Line (see Section 3.8 of these Guidelines) or on the New Substances Website at www.ec.gc.ca/substances/

Four Corners Agreement. Canadian and American chemical industries have explored with both Environment Canada and the U.S. EPA, ways in which the 5 year interval for NDSL listing can be reduced, and benefits of reduced information requirements can be achieved. One way to do so is to facilitate sharing of information used by the U.S. EPA's New Chemicals Program with their counterparts in Canada, and vice versa.

The result of these consultations has been an information sharing pilot project and associated agreement between the governments of the United States (U.S. Environmental Protection Agency) and Canada (Environment Canada and Health

Canada), the Industry Coordinating Group for CEPA, and the U.S. Chemical Manufacturers Association (the "4 Corners" parties). The procedures laid out in the agreement have encouraged voluntary sharing of information between countries while protecting the confidentiality of any information and providing industry with opportunities to reduce testing costs, assessment fees and time to market.

The pilot began in 1996 and lasted until 1998. In September 1998, the "4 Corners" parties met and generally agreed that there were enough positive outcomes to shift from a pilot project to an on-going program, and to renew the agreement with a number of constructive modifications. These include establishing target timelines for completing the review of industry submissions by Environment Canada and Health Canada, and calling for a biennial review of the program, its costs, benefits and improvements. The renewed agreement took effect June 23, 1999 and will continue indefinitely unless modified or terminated.

Embodied in the new agreement is a recognition that while having a substance added to the NDSL is the greatest benefit, it is not the only one. Due to the significant and rising costs of testing, individual companies that make Four Corners submissions may also benefit by obtaining waivers for some of the additional information requirements that they would face for substances not yet appearing on the NDSL.

The Four Corners Agreement will be of greatest benefit to companies having a genuine intent to manufacture or import substances in such quantities and within timelines where there will be a clear advantage over waiting 5 years for the routine updates based on the TSCA Inventory. Where this is not the case, government agencies do not encourage submissions since the effort required to respond represents a significant resource burden with consequences for other aspects of their programs.

A number of documents are available that will facilitate completion of Four Corners submissions including:

- Administrative Procedures for Data Sharing;
- US and Canadian application forms;
- US and Canadian "Limited Permission to Disclose" forms; and
- Guidelines for Canadian Importers and Manufacturers for Implementation of EPA/EC Information Exchange Agreement.

3.4 Transitional Substances

Substances, not listed on the DSL, that were manufactured or imported in a quantity greater than 20 kg in any calendar year during the transitional period (between January 1, 1987 and July 1, 1994) are defined as transitional substances. The information requirements and notification time periods for transitional substances vary depending on when "trigger quantities" were exceeded. The prescribed dates for notifying transitional substances are described in Section 3.6 of these Guidelines.

If a trigger quantity was exceeded during the transitional period, then the notifier is subject to the transitional provisions of subsection 81(2) of the CEPA, 1999. Subsection 81(2) allows the manufacture or import of transitional substances to continue after July 1, 1994, if the prescribed information was provided to Environment Canada before a prescribed date. However, notification is not necessary if the manufacture or import of the transitional chemical was discontinued before July 1, 1994.

3.4.1 Chemicals and Polymers

The provisions for transitional chemicals and polymers expired on June 30, 1999, five years after the NSNR under CEPA came into force. When the most comprehensive information package (Schedule II or VII) was received, in its entirety, prior to June 30, 1999, no additional notification obligations were imposed under the NSNR and the substance was eligible for DSL listing if it met the other listing criteria.

When the NSNR were put in place, they provided notifiers with two options to notify transitional substances (refer to Subsection 3.6.1). For transitional substances notified under Option 2, all complete Schedules II or VII had to be submitted on or before the dates prescribed by subsections 15(2) or 28(3) of the NSNR, all of which preceded June 30, 1999. Therefore, the June 30, 1999 deadline did not apply to these transitional substances.

If complete Schedules II or VII, for transitional substances notified using Option 1, were not filed by June 30, 1999, then the provisions for those transitional substances require higher notification requirements as follows:

For chemicals:

A Schedule II notification must be submitted at least 45 days prior to exceeding 5 000 kg/yr or an accumulated total of 25 000 kg. A Schedule III notification must be submitted at least 90 days prior to exceeding 10 000 kg/yr or an accumulated total of 50 000 kg/yr if the substance is not listed on the NDSL.

For substances previously notified as transitional and now listed on the NDSL, it is not necessary to re-file a Schedule I notification to take advantage of the higher trigger quantities associated with NDSL substances, even if a final notification was not submitted prior to June 30, 1999.

Figure 2 should be used to determine if and when a Schedule III is due for transitional chemicals after June 30, 1999.

For polymers:

A Schedule VII notification must be submitted at least 45 days prior to exceeding

10 000 kg/yr or an accumulated total of 50 000 kg or a Schedule VIII notification must be submitted at least 90 days prior to exceeding 10 000 kg/yr or an accumulated total of 50 000 kg.

The flow diagram on pages 44 and 45 should be used to determine if and when a Schedule VII or VIII is due for transitional polymers after June 30, 1999. In the first box below the Scheme A box, the statement "Polymer/biopolymer is transitional" is no longer applicable as of July 1, 1999.

3.4.2 Biochemicals and Biopolymers

The provisions for transitional biochemicals and biopolymers will expire on September 1, 2001, five years after the Biotechnology portion of the NSNR under CEPA came into force. When the most comprehensive information package (Schedule II or VII, accompanied by the required information under Schedule XIV) is received, in its entirety, prior to September 1, 2001, no additional notification obligations will be imposed under the NSNR and the substance will be eligible for DSL listing if it meets the other listing criteria.

When the NSNR were put in place, they provided notifiers with two options to notify transitional substances (refer to Subsection 3.6.1). For transitional substances notified under Option 2, all complete Schedules II or VII (accompanied by the required information under Schedule XIV) will have to be submitted on or before the dates prescribed by subsections 15(2) or 28(3) of the NSNR, all of which precede September 1, 2001. Therefore, the September 1, 2001, deadline does not apply to these transitional substances.

If complete Schedules II or VII (accompanied by the required information under Schedule XIV), for transitional substances notified using Option 1, are not filed by September 1, 2001, then the provisions for those transitional substances will require higher notification requirements as follows:

For biochemicals:

A Schedule II notification (accompanied by the required information under Schedule XIV) must be submitted at least 45 days prior to exceeding 5 000 kg/yr or an accumulated total of 25 000 kg. A Schedule III notification (accompanied by the required information under Schedule XIV) must be submitted at least 90 days prior to exceeding 10 000 kg/yr or an accumulated total of 50 000 kg if the substance is not listed on the NDSL.

Figure 2 should be used to determine if and when a Schedule III is due for transitional biochemicals after September 1, 2001.

For biopolymers:

A Schedule VII notification (accompanied by the required information under Schedule XIV) must be submitted at least 45 days prior to exceeding 10 000 kg/yr or an accumulated total of 50 000 kg or a Schedule VIII notification (accompanied by the required information under Schedule XIV) must be submitted at least 90 days prior to exceeding 10 000 kg/yr or an accumulated total of 50 000 kg.

The flow diagram on pages 44 and 45 should be used to determine if and when a Schedule VII or VIII is due for transitional biopolymers after September 1, 2001. In the first box below the Scheme A box, the statement "Polymer/biopolymer is transitional" will no longer be applicable as of September 1, 2001.

3.5 *Annual and Accumulated Quantities*

The notifier must develop an accurate estimate of the annual (calendar year) quantities and the accumulated total amount of the new substance imported and/or manufactured. This information is needed to ensure that additional information requirements are submitted before higher "trigger" quantities are reached. The prescribed trigger quantities relate to the actual amount of substance manufactured and imported, not to the quantity of formulation containing the substance. For example, if 10 000 kg of Formulation A, which contains 13% of new substance *X* is to be imported during a calendar year, then the annual import quantity of substance *X* would be 1 300 kg. Repetition of this yearly 1 300 kg transaction over eight years would result in an accumulated total of 10 400 kg.

For transitional substances, the quantities are calculated from the date that the substance was first manufactured in Canada, or imported into Canada, after December 31, 1986.

3.6 *When to Notify the Government*

The timing of a notification depends on the schedule of information required, and whether the trigger quantity is exceeded during or after the transitional period.

3.6.1 *Notification of Substances Exceeding Trigger Quantities During the Transitional Period*

All transitional substances required a preliminary notification shortly after the Regulations came into force, namely July 1, 1994, for chemicals and polymers, and September 1, 1997, for biochemicals and biopolymers. For chemicals, the information specified in Schedule I must have been submitted by October 1, 1994. For biochemicals, the information specified in Schedule I and items 1-3 of Schedule XIV must have been submitted by December 1, 1997. For polymers, the information specified in Schedule VI or XI must have been submitted by November 1, 1994. For biopolymers, the information specified in Schedule VI and items 1-3 of Schedule XIV or

Schedule XI and items 1-2 of Schedule XIV must have been submitted by January 1, 1998. However, if the transitional substance was not manufactured or imported after the transitional period, no notification was needed.

If additional trigger quantities were exceeded **during the transitional period**, additional notifications are (were) required within a prescribed time after the transitional period. The timing for these subsequent notifications depends on the year that the trigger quantity was exceeded. Please refer to Tables 1 and 1.1 below. For example, if 10 000 kg of a new chemical was imported for the first time in 1989, the information prescribed in Schedule I must have been provided by October 1, 1994, and have been followed by a Schedule II notification no later than January 1, 1996.

Table 1 Notification Periods for Chemicals and Polymers that Exceeded Trigger Quantities during the Transitional Period

Schedule	Year Trigger Quantity Exceeded	Notification Deadline
I	1987 to 1994	October 1, 1994
VI or XI	1987 to 1994	November 1, 1994
II, V, VI, VII, XIII	1987	January 1, 1995
II, V, VI, VII, XIII	1988	July 1, 1995
II, V, VI, VII, XIII	1989	January 1, 1996
II, V, VI, VII, XIII	1990	July 1, 1996
II, V, VI, VII, XIII	1991	January 1, 1997
II, V, VI, VII, XIII	1992	July 1, 1997
II, V, VI, VII, XIII	1993	January 1, 1998
II, V, VI, VII, XIII	January to June 1994	July 1, 1998

Table 1.1 Notification Periods for Biochemicals and Biopolymers that Exceeded Trigger Quantities during the Transitional Period

Schedule	Year Trigger Quantity Exceeded	Notification Deadline
I	1987 to 1994	December 1, 1997
VI or XI	1987 to 1994	January 1, 1998
II, V, VI, VII, XIII	1987	March 1, 1998
II, V, VI, VII, XIII	1988	September 1, 1998
II, V, VI, VII, XIII	1989	March 1, 1999
II, V, VI, VII, XIII	1990	September 1, 1999
II, V, VI, VII, XIII	1991	March 1, 2000
II, V, VI, VII, XIII	1992	September 1, 2000
II, V, VI, VII, XIII	1993	March 1, 2001
II, V, VI, VII, XIII	January to June 1994	September 1, 2001

If no additional trigger quantities were exceeded during the transitional period, the following two options were provided to notifiers.

For chemicals: For chemicals that exceeded 20 kg/yr during the transitional period but did not exceed 5 000 kg/yr or an accumulated total of 25 000 kg, the notifier had the two following options:

Option 1: Submit a Schedule I on or before October 1, 1994, and submit a Schedule II 45 days before the trigger is exceeded.

Option 2: Submit the first part of Schedule II (sub-items 1(1), (2), (3) and (5), portion of sub-item 2(5) and item 4)) on or before October 1, 1994, and the remainder of Schedule II according to the year the 20 kg trigger was exceeded. For example, July 1, 1997 if the 20 kg trigger was exceeded in 1992.

For biochemicals: For biochemicals that exceeded the 20 kg/yr during the transitional period but did not exceed 5 000 kg/yr or an accumulated total of 25 000 kg, the notifier has two options:

Option 1: Submit a Schedule I on or before December 1, 1997, and submit a Schedule II 45 days before the trigger is exceeded.

Option 2: Submit the first part of Schedule II (sub-items 1(1), (2), (3) and (5), portion of sub-item 2(5) and item 4)) on or before December 1, 1997, and the remainder of Schedule II according to the year the 20 kg trigger was exceeded. For example, September 1, 2000 if the 20 kg trigger was exceeded in 1992.

These notifications must be accompanied by the required information under Schedule XIV.

For polymers: For polymers that exceeded 20 kg/yr during the transitional period but did not exceed 10 000 kg/yr or an accumulated total of 50 000 kg, the notifier had two options:

Option 1: Submit a Schedule VI on or before November 1, 1994, and submit a Schedule VII 45 days before the trigger is exceeded.

Option 2: Submit the first part of Schedule VII (sub-items 1(1), (2), (3) and (7), portion of sub-item 2(7) and item 4) on or before November 1, 1994 and the remainder of Schedule VII according to the year the 20 kg/yr trigger was exceeded. For example, July 1, 1997 if the 20 kg trigger was exceeded in 1992.

For biopolymers: For biopolymers that exceeded 20 kg/yr during the transitional period but did not exceed 10 000 kg/yr or an accumulated total of 50 000 kg, the notifier has two options:

Option 1: Submit a Schedule VI on or before January 1, 1998, and submit a Schedule VII 45 days before the trigger is exceeded.

Option 2: Submit the first part of Schedule VII (sub-items 1(1), (2), (3) and (7), portion of sub-item 2(7) and item 4) on or before January 1, 1998 and the remainder of Schedule VII according to the year the 20 kg/yr trigger was exceeded. For example, September 1, 2000 if the 20 kg trigger was exceeded in 1992.

These notifications must be accompanied by the required information under Schedule XIV.

3.6.2 Notification of Substances that Exceed Trigger Quantities After the Transitional Period

Notification of substances (including transitional substances) that exceed the trigger quantity after the transitional period, must be provided within a prescribed time period in advance of the trigger quantity being exceeded . Please refer to Table 2 below.

Table 2 Notification Periods for Substances that Exceed Trigger Quantities after the Transitional Period

Schedule (chemicals)	Notification Period (days before manufacture/import)	Schedule (polymers)	Notification Period (days before manufacture/import)
I	5	VI	45
II	45	VII	45
III	90	VIII	90
IV	21	XI	5
V	21	XII	21
		XIII	21

3.7 *Notification of Product Development Substances*

The Regulations offer the person who is importing or manufacturing product development substances the choice of submitting either the regularly prescribed information or the information listed in the Product Development Plan Schedule IV (chemicals/biochemicals) or XII (polymers/biopolymers). If a Schedule IV or XII is used, the information must be submitted 21 days in advance of exceeding the prescribed trigger quantity.

Product development programs cannot exceed a period of two years. During this period, product development update reports must be submitted every six months, or less, until the program is completed. Update reports must contain all the information and test data relevant to environmental and health hazard identification that has been obtained since the previous report. After the development program has terminated, a request for another product development program can be submitted if the substance is being developed for an alternate purpose.

The Departments of Environment and Health will assess the submitted product development plan and indicate if the plan is adequate. This development plan may not contain test marketing activity, i.e., the exploration of market capability in a competitive situation where the creation or improvement of the substance, or a product containing the substance, is no longer the primary objective.

3.8 *For more information about the NSNR*

Individuals who have technical questions or who require additional information on procedures for new substance notifications or on the status of submitted notifications, may contact Environment Canada Headquarters. Inquiries should be directed to:

New Substances Branch
Environmental Protection Service
Environment Canada
14th Floor, Place Vincent Massey
Ottawa, Ontario K1A 0H3
Canada

Telephone: (800) 567-1999 (toll-free in Canada) - NSN Information Line
(819) 953-7156 (outside Canada)
Facsimile: (819) 953-7155
E-mail: NSN-infoline@ec.gc.ca

Individuals may also visit:

the New Substances website at: http://www.ec.gc.ca/substances/

the Environmental Registry on-line at: http://www.ec.gc.ca/CEPARegistry/

3.9 Supporting Documentation

3.9.1 Notification Forms and Guidelines

Additional copies of the NSN Forms may be obtained from Environment Canada by contacting one of the regional offices (Appendix 2) or Environment Canada Headquarters in Ottawa. NSN Forms may be reproduced without permission.

Additional copies of the guidelines may be obtained from Environment Canada by contacting:

Environmental Protection
Publications
Environmental Technology Advancement Directorate
Environment Canada
Ottawa, Ontario K1A 0H3

Tel.: (819)953-5750
FAX: (819)953-7253
E-mail: epspubs@ec.gc.ca

3.9.2 Inventories

The Domestic Substances List (DSL) and the Non-domestic Substances List (NDSL) are available in hard copy at the Environment Canada, New Substances website: http://www.ec.gc.ca/substances/. Chemicals, biochemicals, polymers and biopolymers are listed by their respective CAS Registry Number while biochemicals that are enzymes are liste dby their IUBMB number. Confidential substances are published using masked identities that are named in a manner prescribed by the Masked Name Regulations (see Section 9 of these Guidelines).

Updates to the DSL and NDSL are published in the *Canada Gazette* within 120 days following the determination that a substance is eligible. The *Canada Gazette* is available in subscribing libraries and institutions as well as in the regional and district offices of Environment Canada (Appendix 2). Published formats of the Lists may be purchased through the following suppliers:

in Canada:

Canada Communication Group (Publishing)
Ottawa, Ontario
Canada K1A 0S9

Telephone: (819) 956-4800
Facsimile: (819) 994-1498

in the United States:

International Specialized Book Services Inc.
5602 NE Hassalo Street,
Portland, OR
U.S.A. 97213

Telephone: (800) 944-6190
Facsimile: (503) 280-8832

in Europe:

Books Express
P.O. Box 10
Saffron Walden
Essex CB11 4EW
England

Telephone: (0799) 513726
Facsimile: (0799) 513248

The following information must be included with the order:

Domestic Substances List - May 4, 1994 publication in Part II of the *Canada Gazette*

Liste intérieure des substances - publication du 4 mai, 1994 dans la Partie II de la *Gazette du Canada*

Non-domestic Substances List — CAT No: EN40-398-1991
Liste extérieure des substances — ISBN: 0-660-56394-0

Section 4 - Technical Information Requirements

The New Substances Notification Regulations contain two categories of prescribed information — "administrative" and "technical" data. Explanations of many of the information requirements prescribed in the various Schedules are provided to assist with the compilation and generation of the technical data prescribed in the NSNR. These explanatory notes elaborate details such as: the naming of substances; the conditions under which various tests are required; and what constitutes complete and adequate information in the opinion of the Departments. Discussions of the prescribed administrative information are provided in Section 8.

4.1 Substance Identity Information

4.1.1 Substance Name

Chemicals must be identified using the exact name of the substance established in accordance with the nomenclature rules of IUPAC or CAS. The name should enable an unambiguous chemical structural diagram to be drawn, unless the substance is considered a UVCB. For UVCB substances, the terms "reaction product of", "compounds with", or other acceptable nomenclature may be used. Examples of UVCB substances are:

(a) carbonic acid disodium salt, reaction products with aniline, p-phenylenediamine, sodium sulphide ($Na_2(S_x)$), sulphur and *p*-toluidine;

(b) amines, rosin, compounds with 6'-(diethylamino)-3'-hydroxy-3-oxo-spiro[isobenzofuran-1(3H),9'-[9H]xanthene]-2'-carboxylic acid and sodium bis[2-hydroxy-benzoato(2-)-O^1,O^2]chromate(1-); and

(c) oils, mint, *Mentha arvensis var. piperascens*, terpene-free.

Additional information on the naming of well-defined and UVCB chemicals can be found in Appendix 3 of these Guidelines.

Biochemicals that are enzymes should be named in accordance with the International Union of Biochemistry and Molecular Biology (IUBMB) nomenclature conventions. Group terms such as protease are not acceptable. The name must uniquely identify a single enzyme.

Polymer and biopolymer nomenclature, including pre-polymers, incorporates the identity of monomers and reactants used in the manufacture of the polymer or biopolymer. The name of the polymer/biopolymer may, or may not, include monomers or other reactants that are either incorporated into the polymer/biopolymer or charged to the reaction vessel at two percent or less by weight. However, these substances must be included in the description of the polymer/biopolymer composition (see Subsection 4.1.10 "Monomers and Reactants"). Examples of polymer nomenclature are:

(a) benzene, ethenyl-, polymer with 1,2-ethanediol, butyl 2-propenoate, (chloromethyl)oxirane, 2,5-furanedione, and methyl 2-methylpropenoate; and

(b) formaldehyde, polymer with (chloromethyl)oxirane, 4-(1,1-dimethylethyl)phenol, 4,4'-(1-methylethylidene)bis[phenol], methyloxirane polymer with oxirane ether with 1,2,3-propanetriol [(3:1)] and oxirane.

4.1.2 Masked Name

If the substance identity is claimed as confidential, a masked name must be provided in accordance with the Masked Name Regulations. Procedures for generating masked names are described in Subsection 9.2.2 of these Guidelines.

4.1.3 Chemical Abstracts Service Registry Number

The most precise CAS Registry Number available for the substance must be obtained. For example, CAS Registry Number 68527-02-6* (chlorinated olefins (C_{12}-C_{24})) would not be acceptable for (Z)-1-chloro-5-dodecene; the acceptable CAS Registry Number for this substance is 71673-24-0. The requirement for providing the CAS Registry Number depends on the Schedule of information:

(a) for Schedules IV and XII, the CAS Registry Number should be provided only if the notifier possesses the number;

(b) for Schedules I, V, XI, and XIII the CAS Registry Number should be provided if it already has been assigned to the substance; and

(c) for Schedules II, III, VI, VII, VIII, the CAS Registry Number must be provided if the CAS is able to assign a number. This provision does not apply to substances if the CAS will not assign a Registry Number to a substance because of its confidential status.

Sources of existing CAS Registry Numbers are described in Appendix 4. To obtain information on CAS Registry Numbers, contact:

Chemical Abstracts Service
2540 Olentangy River Road
P.O. Box 3012
Columbus, OH
U.S.A. 43210
Telephone: (614) 447-3600
(800) 848-6538 Ext 3731 (Canada and United States)
Facsimile: (614) 447-3713

4.1.4 International Union of Biochemistry and Molecular Biology Numbers

The most precise fourth level IUBMB Number available for biochemicals that are enzymes must be obtained. For example, IUBMB number 1.1.2 would not be acceptable for Mannitol dehydrogenase (cytochrome); the acceptable IUBMB number for this substance is 1.1.2.2. Note that IUBMB Numbers are also commonly referred to as Enzyme Classification (EC) Numbers in various publications.

IUBMB Numbers can be obtained from a publication made for the IUBMB by Academic Press, Inc.

To obtain a copy from the U.S.A., contact:

Academic Press, Inc.
1250 Sixth Avenue
San Diego, CA 92101-4311
U.S.A.

To obtain a copy from the United Kingdom, contact:

Academic Press, Inc.
24-28 Oval Road
London NW1 7DX
England

IUBMB Numbers can also be obtained from a Web site at:

http://www.chem.qmw.ac.uk/iubmb/enzyme

4.1.5 Structural Formula

The structural formula diagram must clearly indicate the identity of all atoms, type of bonds, ionic charges, and the stereochemistry. Carbon atoms in ring systems and their attached hydrogen atoms need not be explicitly shown. Where applicable, proportions of isomers or tautomeric forms must be indicated.

For UVCB substances, the name and, if known, CAS Registry Number of immediate precursors is required. Substance names may include a description of the synthesis (e.g., acetylation, alkaline hydrolysis) and, where applicable, the range of possible compositions [e.g., paraffins (petroleum), normal C_{5-20}].

For polymers/biopolymers, the structural formula should consist of a simple representative diagram that illustrates the key structural features of the polymer/biopolymer molecule (e.g., types of linkages, functional groups, range, and typical values for the number of repeating units). In addition, the type of polymerization (e.g., graft, block, random) must be indicated.

Additional information and examples of structural formulae are provided in Appendix 3 of these Guidelines.

4.1.6 Molecular Formula

The molecular formula is only required for polymers/biopolymers. The empirical formula must be provided and should identify each of the monomer units. Examples are:

(a) methyl methacrylate, polymer with ethyl acrylate
$(C_5H_8O_2 \times C_5H_8O_2)_x$; and

(b) polyoxyethylene sorbitol tetraoleate
$(C_2H_4O)_n(C_2H_4O)_n(C_2H_4O)_n(C_2H_4O)_n(C_2H_4O)_n(C_2H_4O)_nC_{78}H_{142}O_{10}$

4.1.7 Molecular Weight

The gram molecular weight is only required for chemicals/biochemicals with a definite structural formula. For UVCB substances, an estimate or range of molecular weights must be provided, if known. The number-average molecular weight for polymers/biopolymers is discussed in Subsection 4.2.2.1.

4.1.8 Impurities and their Concentration

Impurities are substances not necessary for the intended use of the product. Impurities are usually present in the final product in low concentrations and may include unreacted starting materials (including microorganisms if a reaction precursor was a biotechnology product) and reaction by-products. The name, CAS Registry Number, and percentage by weight of each impurity must be given, if known.

4.1.9 Additives and their Concentration

Additives are deliberately introduced into a product, and include stabilizers, emulsifiers, and anti-oxidants. The name, CAS Registry Number, and percentage by weight of additives that are essential for marketing must be given.

4.1.10 Monomers and Reactants

Monomers and reactants include compounds such as initiators, cross-linking agents, chain-terminating agents, and chain-transfer agents that are intended to become part of the polymer/biopolymer. The name, CAS Registry Number, and percentage by weight of each monomer and reactant must be given. Monomers or reactants, either incorporated into the polymer/biopolymer or charged to the reaction vessel at two percent or less by weight in the manufacture of the polymer/biopolymer, must also be reported even if they were not included in the name of the polymer/biopolymer.

4.1.11 Material Safety Data Sheet

The Material Safety Data Sheet (MSDS), as defined in Paragraph 11(1) of the *Hazardous Products Act* and detailed in the Controlled Products Regulations, must be provided if one has been prepared.

4.2 Experimental Data

Prescribed and alternative test protocols, as well as laboratory practices, that are acceptable for the generation of experimental data are described in Section 5. Explanations of the conditions under which waivers of prescribed information may be granted are described in Section 6, and examples are given in Appendix 5.

4.2.1 Physical–Chemical Data — Chemicals and Biochemicals

4.2.1.1 Melting and Boiling Point. A melting or boiling point between -50°C and 300°C must be provided as a single value or a range of values. However, if the value is outside this temperature range the information may be indicated as "< -50°C" or "> 300°C". In cases where the substance undergoes a chemical reaction (e.g., degradation, rearrangement) at a temperature below the melting or boiling point, that temperature must be reported. In addition, a pour point, softening point, or sublimation point may be provided instead of a melting point, when this is appropriate.

4.2.1.2 Fat Solubility. Fat solubility is required for all chemicals/biochemicals subject to Schedule III notification, whereas, Schedule II specifies that this information is only required for substances with water solubility less than 10^{-6} g/L.

4.2.1.3 Vapour Pressure. The vapour pressure is not required if the chemical/biochemical has a boiling point of less than 0°C.

4.2.1.4 Octanol–Water Partition Coefficient. The octanol–water partition coefficient is not required if the water solubility of the chemical/biochemical is less than 10^{-6} g/L.

4.2.1.5 Particle Size or Fibre Length Distribution. The particle size or fibre length distribution of the chemical/biochemical only needs to be provided if the chemical/biochemical is a solid with a water solubility of less than 10^{-6} g/L.

4.2.1.6 Hydrolysis as a Function of pH. This test is required for: chemicals/biochemicals that are subject to Schedule V (site-limited intermediates, and export only) and will be transported; chemicals/biochemicals subject to Schedule III; and NDSL chemicals/biochemicals subject to Schedule II. The identity of any known hydrolysis products must also be provided.

4.2.1.7 Adsorption–Desorption. This test is required for chemicals/biochemicals subject to Schedule III, and NDSL chemicals/biochemicals subject to Schedule II. The desorption part of this test is not necessary if less than 25% of the chemical/biochemical is adsorbed during the initial portion of the test. Under these circumstances, a request for a waiver of desorption information is not required.

4.2.1.8 ***Spectroscopy.*** At least one spectrum suitable for characterization of the chemical/biochemical is required. Details of the methodology used (e.g., solvent, ionization technique, field strength, band width, instrumentation) must also be provided.

4.2.2 Physical–Chemical Data — Polymers and Biopolymers

Generally, if the polymer/biopolymer is available in a series of different molecular weight compositions, information must be developed using the lowest number-average molecular weight composition. However, pre-existing information developed on higher molecular weight compositions will also be considered.

4.2.2.1 ***Number-average Molecular Weight.*** The number-average molecular weight must be determined on the composition having the lowest average molecular weight of any composition intended for import or manufacture. This information is not required for polymers/biopolymers that are subject to Schedule XIII (site-limited and export only) and will not be transported. Procedures are given in Section 1 of Appendix 6 "Polymer/Biopolymer Test Methods".

4.2.2.2 ***Residual Constituents with Molecular Weights of Less than 500 daltons and Less than 1000 daltons.*** The percentage of residual constituents must be determined on the composition that has the lowest average molecular weight of any composition intended for import or manufacture. This information is not required for polymers/biopolymers that are subject to Schedule XIII (site-limited and export only) and will not be transported. Procedures are given in Section 2 of Appendix 6 "Polymer and Biopolymer Test Methods".

4.2.2.3 ***Water Solubility.*** Water solubility at pH 7 is required for polymers/biopolymers that are subject to Schedule VII or VIII, and for polymers/biopolymers that are subject to Schedule XIII (site-limited and export only) and will be transported. This requirement is not applicable if the solubility in water can be shown to be less than 10 mg/L. For polymers/biopolymers subject to Schedules VII or VIII, solubility at pH 1 and 10 is also required, unless the solubility at these pH values is less than 50 mg/L.

Additional information on water solubility testing for polymers/biopolymers is given in Section 3 of Appendix 6 "Polymer and Biopolymer Test Methods".

4.2.2.4 ***Dispersibility in Water.*** The degree of dispersibility need not be determined; however, if the polymer/biopolymer is intended to be formulated for dispersal in water, this must be stated.

4.2.2.5 ***Hydrolysis as a Function of pH.*** Hydrolysis as a function of pH is only required for polymers/biopolymers that are subject to Schedule VIII and have a solubility in water of more than 50 mg/L. The identity of any known hydrolysis products must also be provided. Additional information on hydrolysis of polymers/biopolymers is given in Section 4 of Appendix 6 "Polymer and Biopolymer Test Methods".

4.2.2.6 ***Ultraviolet-visible Spectrum.*** An ultraviolet-visible spectrum that can be used to determine the potential for photodegradation of the polymer/biopolymer is required. Therefore, the wavelength range from 290 to 700 nm must be covered. The methodology used (e.g., solvent, instrumentation, band width) must also be provided.

4.2.2.7 ***Solubility in n-Octanol.*** Solubility in n-octanol is not required if the octanol solubility is less than 50 mg/L. If the polymer/biopolymer is subject to Schedule VII or VIII, either the octanol–water partition coefficient or the octanol solubility can be provided.

Additional information on n-octanol solubility testing for polymers/biopolymers is given in Section 5 of Appendix 6 "Polymer and Biopolymer Test Methods". This information is not required for polymers/biopolymers that are subject to Schedule XIII (site-limited and export only) and will not be transported.

4.2.3 Toxicological Data

4.2.3.1 ***Acute Mammalian Toxicity.*** Test animals must be dosed using the same route(s) of exposure that is (are) anticipated to be the most significant route(s) for potential human exposure. The most significant route of potential human exposure for these Regulations refers to exposure of the general population in Canada. To select the most appropriate route for testing, the expected level of the substance in the various environmental media and consumer products, and the bioavailability of the substance through ingestion, inhalation, and dermal absorption must be considered. The most significant route of exposure to a substance for the general population may be different from exposures for workers in an occupational setting. Consequently, data generated for occupational exposures may not meet the requirement for "the most significant route of potential human exposure" specified in the Regulations. If it is not evident which route(s) would be the most appropriate for testing under CEPA, 1999, Health Canada (Section 7) should be consulted.

Acute mammalian toxicity testing is not required for chemicals/biochemicals that are subject to Schedule V, or for polymers/biopolymers that are subject to Schedule XIII and will not be transported.

4.2.3.2 ***Skin Irritation and Skin Sensitization.*** In most cases, properly conducted human patch tests (positive or negative response) are an acceptable alternative to animal testing for skin irritation or skin sensitization. Human-use experience may also be an acceptable alternative to the prescribed test protocols for toxicological endpoints, especially skin irritation or skin sensitization tests (positive response only). The human-use experience must be well-described, and give particular emphasis to quantifying the exposure as accurately as possible. Anecdotal information from persons handling or exposed to the substance is not an acceptable surrogate for performing a prescribed test.

4.2.3.3 **_Repeated Dose Mammalian Toxicity._** A test report from a study of at least 28-days duration must be submitted unless a 14-day test was performed before publication of the Regulations in *Canada Gazette*, Part II. In that case, data from the 14-day test are acceptable. As described in Subsection 4.2.3.1 "Acute Mammalian Toxicity", test animals must be dosed using the most significant route of potential exposure for the general population in Canada.

4.2.3.4 **_Mutagenicity._** Schedule II requires an *in vitro* test for gene mutation, chromosomal aberrations in mammalian cells, or another acceptable indicator of mutagenicity that permits an assessment of *in vitro* mutagenicity. The most appropriate test should be selected based on the structure of the substance.

The mutagenicity test requirements in Schedules III and VIII consist of: an *in vitro* test for gene mutation; an *in vitro* test for chromosomal aberrations in mammalian cells; and an *in vivo* mammalian test for gene mutation, chromosomal aberrations, or another indicator of mutagenicity that permits an assessment of mutagenicity acceptable to the Departments. Some flexibility is given in the choice of *in vivo* test to permit the most appropriate test to be chosen for the substance. The choice of *in vivo* test should be based on results from *in vitro* mutagenicity tests, the structure and mechanism of action of the substance, and developments in the field of genotoxicity.

An adequate *in vivo* mutagenicity test must include evidence that the tissue investigated was exposed to the substance or its metabolites. Criteria for "evidence that the tissue investigated was exposed to the substance or its metabolites" and for what constitutes an "indicator of mutagenicity" and an assessment "acceptable to the Departments" are described in Appendix 8.

The actual number and type of mutagenicity tests that must be performed on a substance depends on: the results of other genotoxicity tests; the structural similarity of the substance to known mutagens or carcinogens (or non-mutagens and non-carcinogens); and the anticipated exposure of the substance to humans. If it can be demonstrated that the information from a mutagenicity test is not needed for the assessment, or that the test is not technically feasible, a waiver of that information will be granted (see Section 6). Examples of conditions under which waivers may be granted for mutagenicity tests are given in Appendix 5.

4.2.4 *Ecotoxicological Data*

4.2.4.1 **_Fish and_ Daphnia _Acute Toxicity._** For chemicals/biochemicals subject to Schedule III, both fish and *Daphnia* acute toxicity tests (limit or LC_{50}) are required. For polymers/biopolymers subject to Schedule VII or VIII, data from either a fish or a *Daphnia* test is required on the water soluble portion of the polymer/biopolymer if the water solubility of the polymer/biopolymer is greater than 10 mg/L. However, if the polymer/biopolymer is expected to be cationic in an aquatic environment, data are required from both fish and *Daphnia* acute toxicity tests performed on the entire polymeric substance.

4.2.4.2 ***Algal Acute Toxicity.*** An algal acute toxicity test, performed on regular growth medium, is required for all anionic polymers/biopolymers subject to Schedules VII or VIII. Because the toxicity of polycarboxylic acids may be mitigated by the presence of Ca^{2+} or Mg^{2+} ions, algal toxicity of polycarboxylic acids must also be conducted using a modified algal growth medium (Ca, or Ca and Mg, added to attain a measured hardness of 150.0 mg/L as $CaCO_3$). For polycarboxylic acids used as scale inhibitors, an algal toxicity test must, in addition, be conducted under a third condition (the addition of an equivalent of Ca^{2+} ion to the test compound stock solution).

4.2.4.3 ***Biodegradation.*** Biodegradation data are required for chemicals/biochemicals that are subject to Schedule III, and for chemicals/biochemicals that are subject to Schedule V (site-limited intermediates or export only) and will be transported. For polymers/biopolymers subject to Schedule VIII, biodegradation information is required for the water soluble portion of the polymer/biopolymer if the water solubility of the polymer/biopolymer is greater than 50 mg/L. The biodegradability requirement in Schedule VII is limited to cationic polymers/biopolymers. The identity of any known products of biodegradation must be provided.

4.3 Exposure Information

Information submitted for the following sections should provide sufficient detail to help predict releases into the environment and potential human exposures.

4.3.1 Manufacture Information

For substances manufactured in Canada, manufacture information must include the following:

(a) a brief description of the manufacturing process that details precursors, reaction conditions (e.g., temperature, pressure, catalysts, and reaction stoichiometry), and the nature (batch or continuous) and scale of the process;

(b) a flow diagram of the manufacturing process that includes such features as process tanks, holding tanks, and distillation towers;

(c) the major steps in operations, the chemical conversions, the points of entry of all feedstocks, and the points of release of substances; and

(d) the sites of manufacture and estimates of annual production at each of the sites for the first 12 months, and of production during the maximum 12-month period in the first three years.

For substances imported into Canada, manufacture information must include (if known) the identity of any precursors and a brief description of reaction conditions (e.g., temperature, pressure, catalysts, and reaction stoichiometry).

4.3.2 Import Information

Import information must include:

(a) the name of the importer;

(b) the planned destinations (e.g., manufacturing plants, processing plants, or distribution centres); and

(c) estimates of the annual imports for the first 12 months, and of imports in the maximum 12-month period in the first three years.

4.3.3 Specific Use Information

Use information must include the following (if known):

(a) the intended function, specific application, and any other known uses of the notified substance;

(b) the quantity intended for each application or use;

(c) the sites of formulation, processing, and end use, and an indication of whether the use includes resale or storage;

(d) an indication of whether the use is highly dispersive (paint solvents, aerosol), dispersive (soaps, fabric softeners), non-dispersive (inks, dyes), contained (capacitor fluids, catalysts), consumed (fuels, reaction intermediates), or is in the "other" category; and

(e) the type of use, e.g., industrial (reaction intermediate), commercial (dry cleaning solvent), or consumer (household cleaners, polish). A substance may have uses in more than one category.

Use information should provide sufficient detail to help predict potential human exposure and the likelihood of release into the environment.

4.3.4 Distribution, Storage, and Handling Information

Distribution, storage, and handling information must include:

(a) the expected modes of transport and (if known) the Product Identification Number (PIN)[2], the packaging type (container or bulk), and the concentration of the substance in the marketed preparation;

(b) handling precautions, personal protection equipment, and storage requirements; and

(c) emergency measures, which include first aid measures, procedures for cleanup in case of an accidental spill or release during manufacturing, processing, distribution or storage, and (if known) fire fighting information and possible dangerous reactions.

4.3.5 Disposal Information

Disposal information must include (if known):

(a) a description of the proposed disposal method for consumer, commercial, and industrial applications (e.g., lined landfill site, high temperature incineration, or recycling);

(b) the expected amount of the substance that will be disposed by each method;

(c) provincial waste classification(s); and

(d) the site(s) of disposal.

4.3.6 Environmental Release Information

4.3.6.1 Manufacturing Process. The following information must be provided:

(a) a flow diagram, corresponding to the manufacturing process, that indicates locations where releases from the manufacturing process are likely to occur;

(b) an indication, for each release location, of the physical form of the substance (e.g., powder, dust, solution, mist, vapour), the nature of any carrier medium (e.g., process water or air), the media (air, land, or water) into which the substance will be released, and the anticipated frequency, duration, and rate of release;

(c) an estimate of fugitive emissions (if known);

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[2] The Product Identification Number (PIN) is a four digit code used to describe materials being transported in Canada. These codes are in "Dangerous Goods: Guide to Initial Emergency Response" available through the Canada Communication Group Publishing (see Section 3.9.2 of these Guidelines).

(d) a description of the waste management practices (e.g., scrubbers, precipitators, biological treatment) designed to prevent or minimize the release of the substance in effluents and emissions;

(e) an indication of whether the effluent will enter municipal waste treatment facilities or go directly into surface waters (and identification of those facilities or water bodies, as applicable);

(f) an indication, for effluents and emissions, of the amount of substance expected to be released (as kg/day for continuous operations and kg/batch for batch operations), as well as the average and peak concentrations; and

(g) a contingency plan to deal with unintended releases from the manufacturing processes, including any engineering controls (e.g., recovery trench or dike) in place to prevent widespread release.

4.3.6.2 Import. Provide information that indicates the stages in the import process where emissions or discharges to the environment may occur, and the likely quantities and concentrations of these releases.

4.3.6.3 End-use Activities. If any information on processing by domestic customers is known, potential releases should be described as in Subsection 4.3.6.1 "Manufacturing Process". Potential releases from commercial or consumer products should also be provided (if known).

4.3.7 Human Exposure Information

Estimates of the number of persons (in the general population and in occupational settings) that may be exposed to the substance must be provided (if known). This estimate would include information obtained from studies of the level of exposure to employees, customers, and the public from the use of the substance at each of the stages in the life-cycle of the substance:

(a) manufacturing (including research and development, pilot plant, and commercial production);

(b) transportation and handling;

(c) processing;

(d) storage;

(e) intended use; and

(f) disposal, destruction, and recycling.

Not all individuals in a population may be equally exposed; therefore, when the information is available, the possible routes of exposure at each stage should be included and the exposure should be described as quantitatively as possible.

4.3.8 Analytical Test Methods

4.3.8.1 Below the Reported Median Lethal Concentration (LC_{50}). For substances subject to Schedule III, a full description of, or specific reference to, an analytical method that can detect the substance in water at or below the lowest reported LC_{50} or limit test for fish or *Daphnia*, must be provided. An analytical test method is not needed if the acute aquatic toxicity tests have been waived. In this case, it is not necessary to request a waiver.

4.3.8.2 In the Environment. This information is required for product development substances only (Schedules IV and XII). Analytical test methods must be provided that detect the substance in the environment if the methods are in the person's possession or within reasonable access (see Section 4.5 "Additional Information"). The analytical method(s) capable of detecting the substance in the environment must be described in full, or specifically referenced.

4.4 Other Agencies Notified

Information must be provided of any known circumstances where the import or manufacture of the new substance has been notified to another agency or government, and the purpose of such notification must be given. For example, the Ontario Ministry of Labour may have been notified of the import of a new substance for use in an occupational setting, or an American supplier may have notified the United States Environmental Protection Agency under the premanufacture notification provisions of the *Toxic Substances Control Act* (TSCA).

4.5 Additional Information

All information and data relevant to environmental and health hazard identification must be provided, such as:

(a) experimental data (including negative results);

(b) summaries of literature reviews;

(c) results of searches from databases to which the notifier has access;

(d) structure–activity relationship analyses performed on the substance or structurally related substances; and

(e) results of studies of the risk to employees, customers, public, or the environment (e.g., environmental fate modelling) that may result from the use of the substance.

Additional information encompasses information in the person's possession or to which the person should reasonably have access. "In the person's possession" means information in the company's offices in Canada or, if the notification was submitted by a foreign company through a Canadian agent, the offices in the country where the notification originated. The phrase "to which the person ought reasonably to have access" means information in any of the company's offices worldwide, or other locations where the person can access the information.

Information on possible environmental benefits resulting from the manufacture or use of the new substance should also be provided. Examples of such benefits include:

(a) the substance is a "less toxic" substitute for an existing substance or technology;

(b) the substance is recovered from a waste stream;

(c) the manufacture or use of the substance will generate less waste than an existing substance; or

(d) the substance may be recycled.

Any information provided as "Additional Information" may be provided in the language in which the information was originally prepared.

4.6 Interpretation of "Person" - section 81 of the CEPA, 1999

Section 81 of the CEPA, *1999* applies to the "person" manufacturing or importing a new substance into Canada. Since the New Substances Notification Regulations (NSNR) of the CEPA, 1999 were implemented on July 1, 1994, the interpretation of "person" was restricted to a single corporate entity (the original notifier). This implied that the "transitional" status of substances was lost when sale of assets occurred and transitional substances had to be re-notified as non-transitional substances by successors. Successor owners of non-transitional substances had to re-notify these as new substances and could only commence importing or manufacturing the new substance after the assessment period had expired.

For the purposes of the NSNR, Environment Canada is interpreting the term "person" under section 81 of the CEPA, 1999 as follows:

> "Where one corporation has provided information to Environment Canada under the NSNR concerning a new substance, Environment Canada will consider a successor corporation to be the same "person" as the original corporation for the purposes of s. 81 of the CEPA, 1999 and the NSNR," under the conditions imposed by the Certification Form.

This interpretation applies to both ss. 81(1) and (2) of the CEPA, 1999 (non-transitional and transitional substances). It will reduce duplication of work for both industry and the departments of Environment and Health. For transitional substances, this interpretation will remove the requirement for a company to notify at higher schedules, and the associated costs to industry, which would be associated with the loss of "transitional status" for a notification upon change of ownership of the substances. For non-transitional substances the interpretation permits successors to continue importing or manufacturing a new substance without having to "re-notify" and thus wait for the assessment period to have expired.

Successors wishing to take advantage of the original status of a substance, prior to change of ownership, must sign a Certification Form that can be obtained by contacting the NSN Information Line. The form must be signed by an officer of the successor corporation. A Certification Form must be completed for each substance to which the change of ownership applies.

4.7 Information Sharing Agreements

Instances will occur where a substance has been notified, but it has not been published on the DSL, either because the substance did not meet all of the criteria in section 87 of the CEPA, 1999 or because the assessment or processing of the notification is still in progress. In such cases, a second party intending to manufacture or import that substance will be required to provide a complete notification package. To reduce both duplicate testing and the expense of developing information for a notification, Environment Canada will provide an opportunity to obtain information directly from a previous notifier through the use of an Information Sharing Agreement (ISA).

An Information Sharing Agreement starts when a notifier provides Environment Canada with: (1) documentation of intent to import or manufacture a particular substance; and (2) authorization to release the name of the technical contact within the company to any other company that has met these two criteria. Documentation of intent to import or manufacture a substance may be either a New Substances Notification or the information described in Section 9.3 of these Guidelines. After receipt and acceptance of this documentation, Environment Canada will conduct a search for ISA candidates and, if any exist, will simultaneously provide each company with the name, address, and phone number of the technical contact of the other company or companies. Environment Canada's contribution to the process will end at this point, and the companies may then proceed to negotiate an Information Sharing Agreement. Procedures to indicate willingness to enter into an ISA are described in Section 8.

Section 5 - Test Procedures and Practices[3]

5.1 Organization for Economic Cooperation and Development Test Guidelines

The conditions and test procedures used for the development and reporting of test data must be consistent with the conditions and test procedures of the Organization for Economic Cooperation and Development (OECD) "Guidelines for Testing of Chemicals" that are current at the time of testing.

The appropriateness of the OECD method for the substance must be determined, and any necessary modification should be made (including the use of an alternative method) to ensure the acceptability of test data. Any deviations from the OECD guidelines should be clearly noted and explained. The OECD Test Guidelines are not designed to serve as rigid test procedures appropriate for all substances, rather, they allow flexibility for expert judgement and adjustments to new developments. Therefore, credible alternative procedures (see Section 5.4) are considered consistent with the spirit of the OECD guidelines.

5.2 Good Laboratory Practice

The laboratory practices used to develop test data for a new substance notification must be consistent with the "Principles of Good Laboratory Practice" (GLP) set out by the OECD.

All factors (test procedures and results as well as adherence to OECD GLP) relative to the development of a specific data requirement in a notification will be assessed by the Departments on a case-by-case basis. Such data must include the name and address of the head of the quality assurance unit of the testing laboratory. In addition, for data developed after the Regulations came into force and that employ a non-OECD[4] GLP, provide a description of the GLP including quality control and quality assurance procedures and an indication of reference substances. Notifiers who are uncertain about the suitability of planned GLP may contact the NSN Information Line.

In keeping with commitments to OECD, the Departments of Environment and Health are currently developing a Canadian GLP program based on OECD GLP requirements.

5.3 Health Protection Branch Mutagenicity Test Guidelines

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[3] Sources of information on test procedures and practices are given in Section 5.6.

[4] Laboratory practices that do not meet the requirements of another agency's GLP (e.g., United States Food and Drug Administration) may meet the requirements of OECD GLP.

The Health Protection Branch (HPB) mutagenicity test guidelines should be regarded as the standard methods for developing mutagenicity test data for new substance notifications. The HPB Guidelines are functionally very similar to the equivalent OECD mutagenicity test guidelines; however, they provide additional advice, or different guidance, on the conduct of some tests. The OECD or other mutagenicity test guidelines will be acceptable when, in the opinion of the Departments, they are equally or better suited to measure the mutagenic potential of the substance under investigation.

5.4 Alternative Procedures

Information in support of a notification may also be obtained from alternative test protocols or from calculation or estimation methods. These alternative procedures will be acceptable when, in the opinion of the Departments, they are equally or better suited to measure the endpoint under investigation. Contact the NSN Information Line or refer to the tables in Subsection 5.4.1 to determine if a procedure is acceptable. Requests for waivers of information are not required for the submission of information from an approved alternative procedure.

5.4.1 Alternative Test Protocols

Alternative protocols include other domestic or internationally recognised protocols (e.g., test methods developed by the Departments of Environment or Health, International Organisation for Standardisation (ISO), American Society for Testing and Materials (ASTM), the United States *Federal Insecticide, Fungicide, and Rodenticide Act* (FIFRA), and the United States *Toxic Substances Control Act* (TSCA)). In addition, protocols developed by individual companies or associations may also be acceptable. The method used must be clearly referenced and described in sufficient detail to permit evaluation.

The alternative protocol must provide the desired data to a degree of accuracy acceptable to the Departments and must be described in sufficient detail to allow an evaluation of the procedure and results.

The description of the alternative protocol should include, but not be limited to, a detailed description of the test principles and design, the methodology and controls used, validation studies of the accuracy and variability of the test method in comparison with the prescribed method, and any references to the protocol in the scientific or technical literature. Descriptions of internationally recognized methods (e.g., ASTM, U.S. EPA, ISO) may not need to be provided, but must be referenced. If the data were generated prior to establishment of current standards of laboratory practice and method sensitivity, appropriate government evaluators should be consulted to determine the acceptability of these data.

The alternative protocol will be assessed by government evaluators to determine whether it is acceptable. If the alternative protocol is not acceptable, the submission will be considered incomplete and the assessment period will not commence until data from an acceptable protocol are provided. It is recommended that any alternative protocols, or modifications to OECD protocols, be discussed with appropriate individuals at Health Canada or Environment Canada before carrying out the test. Modifications or additions to the test protocol, or the use of another protocol, may be recommended.

The government supports the use of testing methods that reduce the number of animals used and that minimize animal suffering, when the quality of data generated is not affected. Consequently, the use of limit tests and validated *in vitro* test methods, where appropriate, is encouraged.

In most cases, properly conducted human patch tests (positive or negative response) are an acceptable alternative to animal testing for skin irritation or skin sensitization. Human-use experience may also be an acceptable alternative to the prescribed test protocols for toxicological endpoints, especially skin irritation or skin sensitization tests (positive response only). The human-use experience must be well-described, and give particular emphasis to quantifying the exposure as accurately as possible. Anecdotal information from persons handling or exposed to the substance is not an acceptable surrogate for performing a prescribed test.

Examples of test methods recommended by the Departments of Environment and Health for the generation of physical–chemical, toxicity, and ecotoxicity data are provided in Tables 3 to 6. The acceptability of these test methods depends on the applicability of the method to the substance under investigation. Sources of test methods listed in Tables 3 to 6 are given in Section 5.6 of these Guidelines.

Table 3 Physical–Chemical Test Methods (Chemicals and Biochemicals)

Data Requirement	Schedules	Test Method
Melting Point	II, III	OECD Guideline 102
Boiling Point	II, III	OECD Guideline 103
Density	II, III	OECD Guideline 109
Vapour Pressure	II, III	OECD Guideline 104
Water Solubility	II, III	OECD Guideline 105
Octanol–Water Partition Coefficient	II, III	OECD Guideline 107
IR, UV, Mass, or NMR spectrum	II, III	As appropriate
Dissociation Constant(s)	II, III	OECD Guideline 112
Adsorption–Desorption (screening test)	II[a], III	OECD Guideline 106
Hydrolysis as a Function of pH (preliminary test)	II[a], III, V[b]	OECD Guideline 111
Particle Size Distribution	II, III	OECD Guideline 110
Fat Solubility	III	OECD Guideline 116

[a] Non-NDSL new Schedule II chemicals/biochemicals are exempt from this requirement.

[b] Site-limited intermediates not transported off-site are exempt from this requirement.

Table 4 Physical–Chemical Test Methods (Polymers and Biopolymers)

Data Requirement	Schedules	Test Method
Number-average Molecular Weight	VI, VII, VIII, XII, XIII[a]	See Appendix 6
Residual Constituents with MW <500 daltons and <1000 daltons	VI, VII, VIII, XII, XIII[a]	See Appendix 6
Water Solubility	VII, VIII, XIII[a]	See Appendix 6
Hydrolysis as a Function of pH	VIII	See Appendix 6
Ultraviolet Spectrum	VIII	See Appendix 6
n-Octanol Solubility	VII, VIII, XIII[a]	See Appendix 6

[a] Site-limited intermediates not transported off-site are exempt from this requirement.

Table 5 **Toxicological Test Methods (Chemicals/Biochemicals and Polymers/Biopolymers)**

Data Requirement	Schedules	Test Method
Acute Mammalian Toxicity	II, III, V[a], VII, VIII, XIII[a]	OECD Guideline 401*, 402, 403
Skin Irritation	III, VIII	OECD Guideline 404
Skin Sensitization	III, VIII	OECD Guideline 406
Repeated Dose Toxicity	III, VIII	OECD Guideline 407, 410, 412
Mutagenicity	II, III, VIII	NHW-HPB Guidelines, OECD Guideline 471, 473, 474, 475[b]

[a] Site-limited intermediates not transported off-site are exempt from this requirement.

[b] Data generated in accordance with OECD test guideline 475 (*in vivo* mammalian cytogenetics) are acceptable only if first division cells are analyzed (described in the HPB Guidelines).

* OECD Guideline 401 will be officially deleted one year after the final adoption of the alternative test guidelines (420, 423 and 425) and the accompanying Guidance Document.

Table 6 **Ecotoxicological Test Methods (Chemicals/Biochemicals and Polymers/Biopolymers)**

Data Requirement	Schedules	Test Method
Fish Acute Toxicity	III, VII[a], VIII	OECD Guideline 203, EC/BTM
Daphnia Acute Toxicity	III, VII[a], VIII	OECD Guideline 202, EC/BTM
Algal Toxicity	VII, VIII	EPA Protocol, EC/BTM
Ready Biodegradability	III, V[b], VII, VIII	OECD Guideline 301

[a] NDSL polymers/biopolymers are exempt from sub-item 2(2).

[b] Site-limited intermediates not transported off-site are exempt from this requirement.

5.4.2 *Structure–Activity Relationships*

Relationships exist between the structure of a substance and its physical properties and toxicity. Knowledge of these relationships, particularly within certain chemical groups, can be used to predict the physical, chemical, toxicological, and ecotoxicological properties of a substance.

Data generated using structure–activity relationships (SARs) fall into two main categories: (a) estimates based on qualitative structure–activity relationships ("read-across"); and (b) estimates based on quantitative structure–activity relationships (QSARs). Calculation or estimation methods will be acceptable if the validity of the provided data is demonstrated.

5.4.2.1 ***Qualitative Structure–Activity Relationships.*** Qualitative structure–activity relationships, referred to as "read-across", provide a qualitative estimate of a particular property and are derived from experimental data on a reference substance or substances (substances with a chemical structure closely related to that of the new substance). Read-across data estimates submitted in place of experimental data must be supported by information such as:

(a) physical and chemical properties of the new and reference substance(s) that will help validate the estimate for the test under consideration;

(b) test report(s) for the reference substance(s) for the test under consideration, which must contain sufficient information to assess the test results;

(c) sufficient description of the method used to generate the test data for the reference substance(s) to assess the appropriateness of the method for the particular test, if the method is an alternative protocol;

(d) test data on the notified substance from a range-finding test, if applicable (e.g., a limit test); and,

(e) a structure–activity analysis for the two or more substances under consideration.

The validity of read-across estimates will largely depend on the structural similarity between the notified and reference substance(s). Read-across estimates are thus applicable where: (a) the notified substance possesses a "trivial" structural difference from the reference substance(s); or (b) the structural difference between the notified substance and the reference substance(s) is not considered "trivial" but will affect the property in a manner that can be accurately predicted.

A "trivial" structural difference between two substances is any change from the notified substance that is not reasonably expected to markedly alter the physical–chemical, biological, or toxicological properties of the substance.

Examples of what may constitute a trivial structural change are: (a) a change in a counter ion of a large charged organic chemical (e.g., sodium dodecyl sulphonate to potassium dodecyl sulphonate); or (b) the addition or subtraction of a single methylene group in a long alkyl chain (e.g., $C_{10}H_{22}$ to $C_{11}H_{24}$).

However, trivial structural changes would generally not include such differences as: (a) a change, modification, introduction, or removal of functional groups or multiple bonds; or (b) positional or geometric isomers.

Examples of possible read-across applications include:

(a) if an ester was shown to hydrolyze rapidly, toxicity data (excepting dermal toxicity, irritation, and sensitization) for the alcohol and the acid might be acceptable;

(b) if a high molecular weight substance had repeating units, an estimate of the physical–chemical properties or toxicity of reference substances that possess fewer or more units might be acceptable;

(c) the water solubility of an ionizable substance might be estimated to be greater than an appropriate similar substance that possessed fewer ionizable functional groups and exhibited very high water solubility; and

(d) if complex mixtures had similar carbon ranges, boiling ranges, percentage aromatics, olefinics and heteroatom content, an estimate of the physical–chemical properties or toxicity of reference substances might be acceptable.

Confidence in a read-across estimate will be strengthened if the notified substance lies within a series of substances that have similar structural features and for which reliable data are provided.

5.4.2.2 Quantitative Structure–Activity Relationship Estimates. Quantitative structural–activity relationships provide quantitative estimates of particular properties and are usually generated by computer programs that use either regression analysis or molecular descriptors that mathematically represent the structural components of a molecule. Linear or multiple regression of a particular property against another property (e.g., octanol–water partition coefficient versus water solubility, or vapour pressure versus boiling point) can be used to derive an empirical relationship for one or several classes of chemicals. An estimate calculated using molecular descriptors can be based either on experimental values for each molecular descriptor or on experimental values for several molecules containing a common molecular descriptor.

All QSAR estimates must be validated by determining: whether all of the structural features of the new substance are represented in the equation or by the substances used to generate the estimate; whether the estimate is reasonable in comparison with measured data on structurally similar substances; and whether these substances contain any structures that may invalidate the estimate.

Information to support the acceptance of data based on QSARs should include: (a) a validation of the estimate using the recommended standard procedures for the model (this may include printouts of chemicals and/or structures used to generate the estimate and the experimental data for these chemicals); and (b) the level of confidence associated with the estimate.

5.4.3 *Other Calculation Methods*

Other methods used to calculate data for a notification (e.g., extrapolation of data generated at different temperatures to provide a value at ambient temperature) will be accepted on a case-by-case basis.

5.5 *Test Data on UVCBs and Impure Substances*

Materials derived from natural sources or complex reactions that cannot be characterized in terms of their constituent chemical compounds, because their composition is too complex or variable, are termed UVCB substances. These substances are considered a single substance under the New Substances provisions of the CEPA, 1999; therefore, all tests should be performed on the entire UVCB substance. Where a prescribed test is not appropriate (e.g., melting point), the use of alternative methods should be considered (e.g., softening point). Also, the provision of information on any of the known components of the UVCB substance will assist in the interpretation of data generated on the UVCB substance.

Difficulties may also occur when substances are tested that contain high levels of impurities (e.g., residual starting materials, solvent, and by-products) because impurities can confound the interpretation of test data. Consequently, tests should be performed on a high-purity sample of the substance. However, if further purification of the substance is neither technically feasible nor practical, tests on the crude product may be acceptable. In all cases, the purity of the tested material must be stated. Furthermore, information on the physical–chemical or toxicological properties of any of the impurities will assist in the interpretation of the data generated on the impure substance.

5.6 *Sources of Test Methods*

1. (a) *Organization for Economic Cooperation and Development (OECD) "Guidelines for Testing of Chemicals"*

   (b) *Organization for Economic Cooperation and Development (OECD) "Principles of Good Laboratory Practice"*

Available in Canada from:

Renouf Publishing Company
1294 Algoma Road
Ottawa, Ontario
K1B 3W8

Les Editions La Liberte
3020, chemin Sainte-Foy
Sainte-Foy (Quebec)
G1X 3V6

Federal Publications Ltd.
165 University Avenue
Toronto, Ontario
M5H 3B8

Available internationally from:

OECD
Publications Service
2, rue André-Pascal
75775 Paris Cedex 16
France

2. (a) *"The Assessment of Mutagenicity - Health Protection Branch Mutagenicity Guidelines" (1992)*

   (b) *"Conducting and Reporting of Mutagenicity Tests: Assays Recommended by the Health Protection Branch" (1993)*

Available from:

Office of the Director General
Environmental Health Directorate
Health Protection Branch
Health Canada
Tunney's Pasture
Ottawa, Ontario
K1A 0L2

3. (a) *"Environment Canada. Biological Test Methods: Acute Lethality Test - Rainbow Trout" (July 1990).* Report EPS1/RM/9.

   (b) *"Environment Canada. Biological Test Methods: Acute Lethality Testing -* Daphnia magna*" (July 1990).* Report EPS1/RM/11.

   (c) *"Environment Canada. Biological Test Methods: Growth Inhibition Test Using the Freshwater Algae -* Selenastrum capricornutum" (September, 1992). Report EPS1/RM/25.

Available from:

Environmental Protection Publications
Environmental Technology Advancement Directorate
Environment Canada
Ottawa, Ontario
K1A 0H3

Order by:	Telephone:	1-800-734-3232
	Facsimile:	(819)994-5629
	E-mail:	epspub@ec.gc.ca

4. (a) *"Algal Acute Toxicity Test U.S. Environmental Protection Agency Environmental Effects Testing Guidelines"* (August 1982). EPA 560/6-82-002, PB 82-232992.

Available from:

National Technical Information Service
United States Department of Commerce
5285 Port Royal Road
Springfield, VA
U.S.A. 87007

Section 6 - Waiver of Information Requirements

6.1 Introduction

Under subsection 81(8) of the *Canadian Environmental Protection Act, 1999*, a request to waive the requirement for any of the prescribed information may be made to the Department of the Environment. The decision to grant a waiver will be made, on a case-by-case basis, by officials within Environment Canada and Health Canada based on whether at least one of three criteria have been met. The statutory criteria for a waiver of information that are identified in subsection 81(8) of the CEPA, 1999 are:

" *(a)* *in the opinion of the Ministers, the information is not needed in order to determine whether the substance is toxic or capable of becoming toxic;*

(b) *a substance is to be used for a prescribed purpose or manufactured at a location where, in the opinion of the Ministers, the person requesting the waiver is able to contain the substance so as to satisfactorily protect the environment and human life;*

(c) *it is not, in the opinion of the Ministers, practicable or feasible to obtain the test data necessary to generate the information."*

Waiver requests must be submitted in writing as part of a notification package and should include a well-documented rationale to support the request. Rejection of a waiver request may result in a delay in the assessment (Section 10.1 of these Guidelines). To avoid delays, it is recommended that the proposed waiver request be discussed with appropriate officials at Environment Canada and Health Canada before the notification is submitted (Section 7).

Appendix 5 provides examples of conditions under which waivers may be granted. This list is not intended to be comprehensive, but to describe some independent conditions that, in most cases, would be considered to be sufficient justification to grant a waiver. Waiver requests may also be based on a combination of factors, e.g., physical properties, inherent toxicity, and potential for exposure to the substance.

If the government has granted a waiver of information, then the particulars of the waiver will be published in the *Canada Gazette* in accordance with subsection 81(5) of the CEPA, 1999. The waiver notice will only contain: (a) the name of the person (or company) to whom the waiver is granted; and (b) the type of information to which it relates (e.g., Company X, biodegradability information). The notice will not specify the substance to which the waiver applies.

Substances for which waivers have been granted under Paragraphs 81(8)(a) or 81(8)(c) will be eligible for entry onto the DSL if the criteria under subsection 87(1) of the CEPA, 1999 have been satisfied. Because inclusion of the substance on the DSL without a SNAc may permit unrestricted use, any substance for which waivers have been granted on the basis of limited exposure under Paragraph 81(8)(b) of the CEPA, 1999, may not be entered onto the DSL because the criterion under Paragraph 87(1)(a) of the CEPA, 1999 will not be satisfied (Subsection 10.4.2 of these Guidelines).

When waivers have been granted, the notifier must provide any corrections used in the information to justify and assess the waivers. The Minister may then, if necessary, request the notifier to provide the information item that was waived, or take appropriate control measures.

6.2 *Waivers Requested Under Paragraph 81(8)(a) of the* Canadian Environmental Protection Act, 1999

Waiver requests may be accepted if it can be established that the test is unnecessary to determine the toxicity of the substance. In cases where the requirement for one part of a prescribed test depends on the result of a previous part (e.g., mutagenicity test data), it is suggested that the tests be completed based on a self-evaluation of test results, or a consultation with appropriate officials at Health Canada or Environment Canada. After receipt of the notification, government evaluators will assess the submitted information to determine whether all the appropriate tests were performed.

Examples of situations in which information may be waived on this basis are:

(a) the hydrolysis test may be waived if the substance contains only functional groups that are not known to hydrolyze; therefore, it can be assumed that the rate of hydrolysis of the substance will be very slow, and any data generated would not provide additional insight into the environmental effects of the substance; and

(b) if an *in vivo* mammalian genotoxicity test gave a positive result, the *in vitro* mutagenicity tests may be waived because the substance would be classified as an *in vivo* mutagen and the results of *in vitro* tests would not change this assessment.

6.3 *Waivers Requested Under Paragraph 81(8)(b) of the* Canadian Environmental Protection Act, 1999

Waiver requests may be accepted if it can be established that the substance will be manufactured in a manner that contains it throughout its life-cycle (manufacture, transportation and handling, processing, storage, intended use, and disposal) and sufficient to protect the environment and human health. This condition can be satisfied if the substance will be used for a limited purpose (e.g., a chemical reaction catalyst within a closed system), or if it is manufactured and contained at a location where releases are controlled. Assessment of each request for a waiver will be based on the information supplied and will place particular emphasis on the containment of the substance. Note that this type of waiver (contained throughout its life cycle) is limited to new substances proposed for manufacture. New substances proposed for importation are excluded from the scope of this portion of paragraph 81(8)(*b*).

If a request for a waiver is based on the substance being used for a prescribed purpose, regulations may be made under paragraph 89(1)(f) of the CEPA, 1999. This "prescribed purpose" regulation will specify the information requirement(s) being waived and prescribe the uses that permit the waiver(s) to be granted. If the substance is to be used in a manner not specified in the "prescribed purpose" regulation, the company must either request an amendment to that regulation or supply the waived information. Note that for waivers to be requested and granted on the basis of "prescribed purpose", the appropriate regulation under paragraph 89(1)(*f*) must be in place. Until then, use, manufacture or import of the substance is prohibited unless the "regular" notification process is used.

Substances with a purpose prescribed by a regulation under Paragraph 89(1)(f) will be excluded from the DSL and, therefore, will continue to be a "new" substance under CEPA, 1999. Consequently, a second party planning to manufacture or import that substance will be required to provide all the information prescribed in the New Substance Notification Regulations[5]. However, if the second party intends to use the substance in a manner identical to the prescribed purpose, they may also benefit from the waivers granted in the "prescribed purpose" regulation.

Examples of situations in which information may be waived under Paragraph 81(8)(b) of the CEPA, 1999 are:

(a) the substance is incorporated into a matrix and will not be released from this matrix during its intended use; and

(b) the substance is an isolated reaction intermediate that is not released during manufacture.

Isolated reaction intermediates that exceed quantities defined for site-limited intermediates (described in Subsections 3.2.1.1 and 3.2.2.3 of these Guidelines) are still eligible for waivers under Paragraph 81(8)(b) of the CEPA, 1999.

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[5] Companies are encouraged to contact Environment Canada to determine whether the original notifier is willing to undertake an Information Sharing Agreement (see Section 4.7 of these Guidelines).

6.4 *Waivers Requested Under Paragraph 81(8)(c) of the* Canadian Environmental Protection Act, 1999

Many of the potential waivers that can be requested under Paragraph 81(8)(c) relate to instances where it is technically arduous or impossible to perform the required tests using conventional technology because of the physical or chemical properties of the substance. Examples of such waivers include:

(a) water solubility determinations for substances that react dangerously with water; and

(b) fat solubility determinations for substances that are highly volatile.

The use of alternative protocols or data to fulfil the information requirement should be considered before it is judged to be infeasible or impractical to provide certain information. The cost of obtaining data cannot alone be used as a reason for the infeasibility or impracticability of providing the prescribed information.

Section 7 - Pre-notification Consultation

Individuals who wish to consult with Environment Canada and/or Health Canada during the planning or preparation of their notification may indicate this desire through the NSN Information Line. These discussions can clarify notification procedures or information requirements, and assist in determining the acceptability of:

(a) waiver requests;
(b) test protocols; or
(c) data based on calculation or estimation methods (e.g., structure–activity relationships)

Discussions will take place after a preliminary package has been submitted that contains sufficient information to permit government officials to make an informed response to the question at hand. The government will make every effort to respond to a query within a period equivalent to the assessment period for that substance. For example, for substances that will be subject to Schedule II requirements, a response should be issued within 45 days.

Officers from the Departments of Environment and Health will give opinions based on the information package tabled at the time of the pre-notification dialogue. The professional opinions of assessment officers expressed during the pre-notification dialogue are not an official commitment because technical conclusions may differ after a more in-depth study of the final notification package.

In addition to pre-notification consultations, the government encourages discussions to clarify any other issues related to the New Substances Notification program.

Section 8 - Preparing a New Substances Notification

8.1 The Notification Form

The New Substances Notification (NSN) Form is intended to serve as an aid for complying with the New Substances Notification Regulations of the CEPA, 1999. The NSN Form is divided into two sections: Part A — Administrative and Substance Identity Information; and Part B — Technical Information. Please note that a complete notification must contain the information requirements of Part A and Part B, and all laboratory reports, waiver justifications, and other attachments necessary to fulfil the requirements set by regulation.

The NSN Form should be completed using a typewriter or reproduced using computer software and submitted on hard copy. The Form or sections of the Form may be reproduced as often as required. All information (except for "Additional Information" as described in Section 4.5 of these Guidelines) must be provided in one of the two official languages (English or French). Two copies of the complete notification should be sent by mail or courier to:

Mailing Address:

New Substances Branch
Environmental Protection Service
Environment Canada
14th Floor, Place Vincent Massey
Ottawa, Ontario K1A 0H3

Courier Deliveries:

14th Floor, Place Vincent Massey
351 St. Joseph Blvd.
Hull, Quebec
J8Y 3Z5

Environment Canada will confirm receipt of the notification and provide a NSN Reference Number (Section 10.1 of these Guidelines) that is to be used in all further correspondence concerning that notification.

8.2 Proprietary Information - Foreign Supplier Submissions

Any information submitted to Environment Canada may be claimed as confidential (see Section 9 for details).

If any information is considered confidential by the Foreign Supplier, the NSN is identified as a "Foreign Supplier Submission". The Canadian Importer must initiate the NSN by providing all the administrative information (Blocks A.1 to A.10) and any other information they have in their possession pertaining to the substance. The confidential information required to complete the NSN may be submitted directly to Environment Canada by the Foreign Supplier once the Canadian Importer has initiated the NSN and has been provided with a NSN Number. If several Canadian companies are importing the same substance from the same Foreign Supplier, each Canadian Importer must submit the appropriate NSN to Environment Canada and is responsible for tracking yearly and cumulative volumes of the imported substance. Each NSN will be assigned a different NSN Number.

For Foreign Supplier Submissions, if the Foreign Supplier has already submitted the confidential information on a substance for one Notifier (Canadian Importer), the same information does not need to be resubmitted for other Canadian Importers. However, a letter of authorization from the Foreign Supplier must be sent to Environment Canada allowing cross referencing and use of the information within the original NSN to complete subsequent notifications by other Canadian Importers of the same substance.

8.3 Completing the New Substances Notification Form

To assist you in completing the NSN Form, explanations of the various administrative information requirements are provided. The alpha-numeric character associated with these explanations corresponds with the appropriate block on the NSN Form. Explanatory notes on many of the technical information requirements are given in Section 4.

8.3.1 Part A - Administrative Information and Substance Identity

A.1 Certification Statement

The person named in this block as providing information is considered to be the notifier and must sign the certification statement. The signature is an affirmation by the notifier that the information and the statements provided in this notification are accurate and true to the best of his/her knowledge. If the notifier is not a Canadian resident, the Canadian agent must also sign this statement. All signatures must be original.

A.2 Corporate Headquarters

Provide the name of the Corporation and the address of the Corporate Headquarters regardless of its location. If the Corporate Headquarters is not located in Canada, the notifier must also provide the name and address of a Canadian agent (Block A.4).

When a Canadian company is the Importer of Record, as shown on the Canadian customs documentation, its name and address must be provided in this Block with Block A.4 left blank. Only the signature of the Canadian Importer is required in Block

A.1. The name and address of the Foreign Supplier is not to appear anywhere in the NSN Form except if appropriate as Technical Contact in Block A.5.

A.3 Proposed Site of Manufacture or Port of Entry

If the notified substance is manufactured in Canada, provide the name of the manufacturer and the location of the manufacturing site(s). For substances that are imported, provide the name of the corporation importing the substance and the planned port(s) of entry into Canada. If there is more than one site of manufacture or import, please provide an attachment.

A.4 Canadian Agent

The only situation for which a Canadian Agent is required is as follows. The name, address and signature of a Canadian Agent must be provided when a foreign company possesses a "Canadian Importer Status" and is the Importer of Record on the Canadian Customs documentation for the substance being imported. In these circumstances the appropriate way to fill in the NSN Form is to provide the name and address of the Foreign Importer in Block A.2 (Corporate Headquarters), and the name and address of the Canadian Agent in Block A.4. Block A.1 must be signed by both the Foreign Importer and Canadian Agent. If the Foreign Importer has more than one Canadian customer for the same substance, NSNs are not required for each customer as the Foreign Importer is recognized as the Importer of Record. Yearly and cumulative imported volumes should be tracked by the Canadian Agent and Foreign Importer to ensure that subsequent NSN obligations are met.

If the corporate headquarters is not in Canada and the name and address of a Canadian Agent has not been provided, the notification will be considered incomplete and will be returned.

A.5 Technical Contact

The name of an individual who is familiar with the content of the notification and can assist in the resolution of issues pertaining to ambiguous, incomplete, or missing information must be provided. Identify this person by name, position, company, address, and telephone and facsimile numbers. The technical contact need not be a resident of Canada.

A.6 Amount

Indicate the trigger quantity that the notifier expects to exceed on the date given in Block A.7.

A.7 Date of Exceedence

Provide the date on which manufacture or import is anticipated to exceed the trigger quantity selected in Block A.6.

A.8 Activity

Check the appropriate block to indicate whether the substance will be manufactured and/or imported.

A.9 Schedule Information

Circle the appropriate Roman numeral to indicate the schedule provided and mark the box with an "X" to indicate substance type (chemical, biochemical, polymer, biopolymer, Research and Development, on NDSL, etc.).

A.10 Correspondence

Indicate the preferred official language of correspondence.

A.11 Substance Information

Environment Canada must receive complete and unambiguous identification of the new substance (Section 4.1 of these Guidelines). If the substance is not adequately identified, the submission will be declared incomplete and returned. This block must be completed even if the substance identity is claimed as confidential.

A.11.1 Substance Name

Mark the appropriate block to specify the use of CAS, IUPAC or IUBMB nomenclature and provide the appropriate name.

A.13 Confidentiality Requests

Notifiers must enter either a "C" to indicate that the information is considered confidential or an "N" to indicate that the information is considered non-confidential. If the information is considered confidential, the notifier should attach the supplementary information detailed in Subsections 9.2.1 and 9.2.2 of these Guidelines.

Entering a "C" in the respective claim box infers the following:

> **Corporation:** The link of the substance identity to the corporation or persons in any or all of Blocks A.2 to A.5 is confidential.

Manufacture: The fact that the corporation identified in Block A.2 manufactures the substance for commercial purposes at the site identified in A.3, or at any site indicated on any attachment provided with this form, is confidential.

Import: The fact that the corporation identified in Block A.2 imports the substance for commercial purposes at the port of entry identified in A.3, or at any port of entry indicated on any attachment provided with this form, is confidential.

Amount: The amount of substance the notifier anticipates exceeding as well as the expected date of the exceedence is confidential.

Substance Identity: The identity of this substance is confidential. The supplemental information described in Subsection 9.2.2 of these Guidelines (Masked Names) must also accompany these claims.

A.14 Information Sharing Agreement

Where a notifier is willing to enter into an Information Sharing Agreement (see Section 4.7 of these Guidelines), the Information Sharing Agreement Authorization must be signed. If authorization is denied, strike a line through Box A.14 and do not sign the statement.

8.3.2 Part B - Technical Data

Part B of the notification form contains seven portions:

B.1 Physical–Chemical Properties;
B.2 Mammalian Toxicity;
B.3 Ecotoxicity;
B.4 Exposure Information;
B.5 Other Agencies Notified;
B.6 Information for Biochemicals and Biopolymers
B.7 Additional Information.

Explanatory notes for many of the technical information requirements are given in Section 4.

8.3.2.1 Experimental Data. Test reports included with the notification must be consistent with the format described in the "Test Report" section of the appropriate test guideline or protocol (Section 5 of these Guidelines). Summaries of test reports are not sufficient. Reports must include the name and address of the head of the quality assurance unit of the testing laboratory. In addition, for data developed after the Regulations came into force and that employ a non-OECD GLP, provide a description of the GLP including quality control and quality assurance procedures and an indication of reference substances. Test reports submitted in a previous New Substances

Notification or section 70 notice need not be resubmitted; however, the appropriate Reference Number must be supplied (see "P" code in Subsection 8.3.2.4).

Although physical–chemical data will be included in test reports, values and conditions should also be provided in Section B.1 of the form. This section of the form will act as a worksheet to help the submitter prepare a rationale to support a waiver request, describe non-applicable information, and discuss notifications with review officers.

For polymers/biopolymers, two information requirements, "dispersibility in water" and "physical state", do not require quantitative determinations. The requirement for dispersibility in water will be satisfied by indicating "yes" or "no"; whereas, the requirement for physical state will be satisfied with an appropriate term (e.g., "solid", "wax", or "liquid"). These responses are to be provided in the appropriate value column of the notification form.

8.3.2.2 Research and Development Activity. This provision is required only for research and development polymers/biopolymers subject to the information requirements of Schedule XI. This provision requires a brief statement of the research activity that is being conducted and should not normally exceed a few sentences in length.

8.3.2.3 Information Available on Material Safety Data Sheets. If any of the information specified in Subsections 4.3.4 or 4.3.5 of these Guidelines is described in sufficient detail on the MSDS, the appropriate section of the MSDS can be referred to in the Attachment column of the Notification Form.

8.3.2.4 Data Codes, Attachments, and Confidential Information. In addition to the list of information requirements, each section contains a column to indicate Data Code, Attachment Reference, and Confidential Information. The section for Physical–Chemical Properties also contains a column for Values and Conditions. Explanations for the use of these columns also appear on the form.

Data Codes. The Data Code is a reference to indicate: whether data are provided; the type of data; or whether a request for waiver of information is being submitted. The Data Codes with explanatory notes are:

D = test data on notified substance, recommended test protocol

> The data provided have been generated on the notified substance using protocols listed in Tables 3 to 6 of these Guidelines. This code is to be used even if the information is provided under the Additional Information requirements of the Schedules (refer to Section 4.5 "Additional Information" of these Guidelines).

F2

A = alternative procedures

The data provided have been generated using: (1) an alternative test protocol; (2) structure–activity relationships including "read-across" and QSAR; or (3) other calculation methods (refer to Section 5.2 of these Guidelines). This code is to be used even if the information is provided under the Additional Information requirements of the Schedules (refer to Section 4.5 "Additional Information" of these Guidelines).

W = waiver requested

Requests for waiver of information must be accompanied by justifications that satisfy any of the waiver criteria listed in subsection 81(8) of the CEPA, 1999 (refer to Section 6 of these Guidelines.)

N/A = not applicable

This code is used if the regulations specify that the provision of information is not required under certain conditions. For example, the octanol–water partition coefficient is not required when the water solubility is less than 10^{-6} g/L. This code cannot be used as an abbreviation for "not available".

NR = not required

This code should appear when the information has not been provided and is not required by regulation.

P = previous notification

This code is to be used if the notifier has already provided the information to Environment Canada in a previous New Substances Notification or a section 70 notice. The applicable NSN or section 70 Reference Number must be entered in the Attachment column.

Attachments. Indicate a reference for accompanying documents (e.g., Appendix 6) so they may be readily located within the notification package. Attachments include: justifications for waivers of information; reports of experimental procedures; reports of test results; rationale for alternative data; results and validation of modelling studies; rationale for why information is considered "not applicable"; or information supplemental to a request for confidentiality.

Confidential Information. Notifiers must enter either a "C" to indicate that the information is considered confidential or an "N" to indicate that the information is considered non-confidential. If the information is considered confidential, the notifier should attach the supplementary information detailed in Subsections 9.2.1 and 9.2.2 of these Guidelines.

Section 9 - Confidential Information

Under section 313 of the CEPA, 1999, any person who provides information to the government may, at the same time, submit a written request that information be treated as confidential. This feature ensures that genuine confidential business information is protected from public disclosure. The degree of protection given to information claimed to be confidential will be consistent with the provisions of the *Access to Information Act* and with sections 314 to 321 of the CEPA, 1999.

9.1 Claiming Confidentiality

The confidentiality privileges described in section 313 of the CEPA, 1999 can be satisfied by: (1) indicating which particular information is confidential using the New Substances Notification Form; and (2) providing the information described in Section 9.2 of these Guidelines.

9.2 Information Supplemental to a Confidentiality Claim

Each claim for confidentiality in a New Substances Notification must be accompanied by the supplementary information detailed in Subsections 9.2.1 and 9.2.2. Environment Canada will review each confidentiality claim to determine whether or not it is valid. Notifiers will be advised if their request for confidentiality is unacceptable and given an opportunity to review and provide additional substantiation for their claim. If the supplementary information is not supplied, the confidentiality claim may not be respected, or alternatively, the company may choose to withdraw the notification.

9.2.1 General Confidentiality Claims

Information supplemental to any request for confidentiality includes a substantiation that the information meets each of the following criteria:

(a) the information is confidential to the company (or person);

(b) the company has taken, and intends to continue to take, measures that are reasonable in the circumstances to maintain the confidentiality of the information;

(c) the information is not, and has not been, reasonably obtainable by third persons by use of legitimate means except with the consent of the company;

(d) the information is not available to the public;

(e) disclosure of the information may reasonably be expected to cause substantial harm to the competitive position of the company; and

(f) disclosure of the information may reasonably be expected to result in a material financial loss to the company or a material financial gain to its competitors.

If these six criteria are met, a claim must be indicated on the notification form, and the Certification Statement appearing on the front of the NSN Form must be signed. The Certification Statement includes the following phrase:

"I hereby certify to the best of my information, knowledge, and belief ... the information for which confidentiality is claimed, meets the criteria for determining confidentiality as outlined in Subsection 9.2.1 of the Guidelines for the Notification and Testing of New Substances: Chemicals and Polymers."

9.2.2 Confidential Substance Identity Claims

Publication of a masked name is required under section 88 of the CEPA, 1999 if publication of the actual identity of a substance would result in the release of confidential business information. Therefore, when claiming confidentiality for substance identity, the notifier must, in addition to the certification described in Subsection 9.2.1, provide the following information per the Masked Name Regulations:

(a) a proposed masked name developed in accordance with the prescribed masking procedure (see Appendix 7);

(b) justification for masking more than one descriptive segment (see Appendix 7); and

(c) the following information:

  (1) the detrimental effects to the competitive position of the company that would result from the identity of the substance appearing on the DSL or in any other publication;

  (2) the manner in which a competitor could use the identity of the substance;

  (3) an indication of whether the identity of the substance has been kept confidential to the extent that competitors do not know it is being manufactured, imported, or used;

  (4) an indication of whether the substance has been patented and, consequently, disclosed through the patent;

  (5) an indication of whether it is public knowledge (e.g., publications in technical journals or trade publications) that the substance is being manufactured, imported, or used for commercial purposes;

(6) the measures that have been taken to prevent undesired disclosure of substance identity and the extent of any disclosures to date;

(7) an indication of whether the substance is, or will be, in an effluent, emission, or waste entering the environment;

(8) an indication of whether the substance is, or will be, in a product available to the public, and whether the substance can be identified by analysis of the product;

(9) the purpose for which the substance is being, or will be, manufactured, imported, or used;

(10) an indication, to the best of your knowledge, of whether Environment Canada, Health Canada, another federal agency, a provincial agency, or the agency of a foreign government has ever made a determination that this substance: (i) has an immediate or long-term effect on the environment; (ii) constitutes, or may constitute, a danger to the environment; or (iii) constitutes, or may constitute, a danger to human life or health (if such a determination has been made, provide details).

9.2.2.1 Masking Substance Identity. The procedures for generating a masked name are also prescribed in the Masked Name Regulations. These procedures are the same as those used in developing the DSL and are described in Appendix 7 of these Guidelines.

Masking a substance name will only be acceptable to the extent necessary to disguise the full identity of the substance, while retaining the generic molecular structure. In most cases, masking a single structural feature should be sufficient; although multiple masking will be acceptable if it can be justified (see Subsection 9.2.2, item b).

If the claim for confidentiality of substance identity is acceptable, the proposed masked name will be evaluated to determine whether or not it is consistent with the Masked Name Regulations. If judged consistent with these Regulations, the masked name will be available for use in publications such as the DSL. If not, inconsistencies will be indicated to the notifier and an alternative name requested. Environment Canada will try to reach a consensus with the company on a masked name. If a consensus is not reached, the government will publish a masked name that, in its opinion, will respect the confidentiality claim of the company while retaining the generic molecular structure of the substance. Alternatively, the company may choose to withdraw the notification.

9.3 Determining the Presence of Confidential Substances on Lists

Substances listed on the confidential portion of the DSL or NDSL are published under masked names. Any person who intends to manufacture or import a substance that they believe to be listed on the confidential portion of one of these lists may seek confirmation from Environment Canada. Environment Canada will only respond to such an inquiry if the person provides Environment Canada with documentation attesting to a *bona fide* intent to manufacture or import the substance for commercial purposes.

To document a *bona fide* intent to manufacture or import, the proponent must supply the following information to Environment Canada at the address provided in Section 3.8 of these Guidelines:

(a) the specific chemical identity of the substance established in accordance with the nomenclature rules of the IUPAC, CAS or IUBMB;

(b) the CAS Registry or IUBMB Number (if available);

(c) a statement, signed by a person residing in Canada, declaring that the person intends to manufacture or import the substance for commercial purposes and that the substance would be subject to the New Substances Notification Regulations if it is not listed on the DSL;

(d) if manufactured in Canada, a description of the research and development activities conducted to date (i.e., information such as manufacturing procedures, quantities manufactured, types of data generated on the substance, and manufacturing history in international commerce), and the intended use of the substance;

(e) if imported, a description of the manufacturing history of the substance in international commerce (if known);

(f) an elemental analysis; and

(g) valid spectral analysis or analyses that confirm(s) the identity of the substance.

If an importer is unable to supply all of the required information because the foreign supplier considers this information confidential, the foreign supplier may submit the information directly to Environment Canada. After the proponent has provided documentation of a *bona fide* intent to manufacture or import the substance, Environment Canada will search the confidential portion of the DSL and NDSL. Environment Canada will respond to a written inquiry into confidential listings within 30 days of receipt of complete documentation and will indicate whether or not the substance is on either of the Lists.

Section 10 - Processing a Notification

This section describes the administrative procedures and responsibilities of the government when a New Substances Notification (NSN) is received.

10.1 Receipt of a New Substances Notification

10.1.1 Assessment "Time Clock"

The assessment "time clock" refers to the allotted time (calendar days) the government has to assess an NSN (see Section 3 of these Guidelines). The assessment periods for substances exceeding trigger quantities after the transitional period correspond with the notification periods listed in Table 2. Substances exceeding trigger quantities during the transitional period have notification periods (Tables 1 and 1.1) but do not have a prescribed assessment period.

Day 1 of an assessment period is the day that the NSN is received by the New Substances Branch, Environment Canada. The assessment time clock may be affected by missing or incomplete information. For example:

(a) if a notification package is grossly inadequate or incomplete, the entire package will be returned and the assessment will begin when a corrected package is received;

(b) if information within the NSN is found to be erroneous and, therefore, the assessment in progress is invalidated, the assessment will be terminated and reset at Day 1 when the correct information is received;

(c) if information within the NSN is found to be erroneous, but does not invalidate the assessment in progress, the assessment time clock will be stopped at Day X and will continue at Day $X + 1$ when the correct information is received;

(d) if minor information is found to be missing or erroneous, the assessment period will continue provided the correct information is supplied by a date specified by an assessment officer; or

(e) if proprietary information is being sent directly to Environment Canada by a foreign supplier, the time clock will not start until all the required information has been received.

10.1.2 New Substances Notification Reference Number

When a New Substances Notification is received by Environment Canada, an NSN Reference Number will be assigned. This number will appear on all correspondence issued by the government concerning that notification and should be used in any subsequent communication regarding that notification.

10.2 Correspondence

Official correspondence between Environment Canada and the notifier or Canadian agent will occur throughout the assessment process. When speed of communication is important, facsimile transmission will be used, with the original following by mail. However, Environment Canada will not send confidential business information (CBI) by facsimile transmission. Environment Canada also advises notifiers not to send CBI by facsimile transmission. The types of correspondence a notifier may receive are:

10.2.1 Acknowledgement

After receipt and preliminary screening of the NSN, an acknowledgement will be issued specifying the starting date of the assessment period and the NSN Reference Number. Acknowledgement indicates that the administrative information is satisfactory and that all required information has been received but not yet reviewed.

10.2.2 Notice of Interruption or Rejection

A rejection or interruption notice will be issued if the NSN contains significant omissions or errors in the mandatory information requirements. These notices will describe all deficiencies in the NSN. Original documentation may be returned.

A rejection notice will be issued if the NSN contains erroneous information that invalidates the assessment in progress. In this case, the assessment will be terminated and reset at Day 1 when the correct information is received.

If the erroneous information does not invalidate the assessment, an interruption notice will be issued indicating that the assessment time clock was stopped at Day *X* (e.g., Day 14 of a 90-day assessment period). Upon receipt of the correct information, the assessment will continue with the time clock re-set at Day X + 1 (e.g., Day 15).

Evaluators will attempt to contact the notifier by telephone to resolve difficulties before a rejection or interruption notice is issued.

10.2.3 Notice of Extension of Assessment Period

When additional time is required to complete an assessment, the notifier will be advised of an extension of the assessment period before the end of the initial assessment period. The government may extend the assessment period only once, for a length of time not exceeding the initial assessment period.

10.2.4 Statement of Assessment Conclusions

The notifier will be advised in writing, before the end of the assessment period, whether or not the government suspects that the substance is toxic or capable of becoming toxic, and what action, if any, will be taken by the government (see Subsection 10.4 of these Guidelines).

10.3 Assessment of the Notification

The purpose of the assessment and control process is to ensure that, either because of the inherent properties of the substance or measures taken to control exposure to the substance, the commercial use of the substance will pose only minimal risk to human health or the environment.

10.3.1 Information Review

Evaluators within Environment Canada and Health Canada will assess the notification package to determine the acceptability of: substance identity and masked names; claims for confidential business information; test protocols and procedures; test data; rationales for requests for waivers of information; and exposure information.

Deficiencies in the submitted information that cannot be easily resolved may result in the rejection of the notification or interruption of the assessment (see Subsection 10.2.2 of these Guidelines).

10.3.2 Assessment for Toxicity

The purpose of the New Substances Notification assessment process is to determine whether or not the substance is, or is suspected of being, "toxic" or capable of becoming "toxic" as interpreted in section 64 of the CEPA, 1999 and stated below:

> *"A substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions*
>
> *(a) having or that may have an immediate or long-term harmful effect on the environment or its biological diversity;*
>
> *(b) constitute or may constitute a danger to the environment on which life depends; or*
>
> *(c) constitute or may constitute a danger in Canada to human life or health."*

Consequently, the determination of whether a substance is, or is suspected of being, toxic or capable of becoming toxic involves assessment of the potential for exposure to humans and components of the environment, and of the adverse effects of the substance on humans or the environment (including other living organisms, interacting natural systems, and the abiotic components of the environment).

The potential for exposure to a substance depends on the quantity, rate, frequency, and conditions of release of the substance into the environment at all points in its life-cycle, as well as the mobility, environmental compartmentalization, and persistence of the substance. The exposure assessment considers the use of the substance identified by the notifier, as well as other possible ways that the substance might be used if it were placed on the DSL without restrictions.

The assessment of adverse effects on humans and other living organisms considers endpoints such as lethality, mutagenicity, reproductive effects, and organ toxicity; whereas, adverse effects on the abiotic components of the environment include consequences such as depletion of the ozone layer, global warming, and production of acid rain.

A substance may be "suspected" of being toxic if either the adverse effects of a substance or the potential exposure to a substance is of concern. For example, substances with considerable potential for exposure because of continuous release of high quantities, or persistence in the environment, may be suspected of being toxic although there may be uncertainty regarding any biological or environmental hazard from the information available for the initial assessment. When an assessment has led to a "suspicion of toxicity", CEPA, 1999 has a unique provision, under subsection 84(1), that permits the government to undertake one of several control options (see Subsection 10.4.1 of these Guidelines).

10.4 Action Taken After an Assessment

After the assessment, the notifier will be advised of whether or not there is a suspicion of toxicity. If there is no suspicion that the substance is toxic or capable of becoming toxic, the notifier may proceed with import or manufacture after the assessment period has expired. When the government suspects that the substance may be toxic or capable of becoming toxic, control measures may be applied to minimize any risk to human health or the environment.

10.4.1 Control Measures

When the government suspects that a substance may be toxic or capable of becoming toxic, the following measures under Section 84 of the CEPA, 1999 may be taken:

(a) permit the manufacture or import of the substance subject to specified conditions;

(b) prohibit the manufacture or import of the substance for a period not exceeding two years (this prohibition lapses at the end of this two-year period unless, before the end of this period, a notice of proposed regulation under Section 93 of the CEPA, 1999 is published in the *Canada Gazette*); or

(c) prohibit the manufacture or import of the substance until supplementary information or test results have been submitted to the government and assessed (the assessment period for this supplementary information expires 90 days after receipt of the information, or at the end of the original assessment period, whichever is the later date).

Measures under section 84 of the CEPA, 1999 must be taken by the government before the expiration of the assessment period. The notifier must comply with these measures or withdraw the notification prior to these measures being imposed.

When a condition or prohibition is issued or altered, a notice must be published in the *Canada Gazette* describing the action and the substance to which it applies. The name of the notifier is not included in this notice. Furthermore, if the publication of the substance name would result in the release of confidential business information, a masked name will be published.

When the government suspects that a significant new activity in relation to the substance may result in the substance becoming toxic, a SNAc notice may be issued under section 85 of the CEPA, 1999.

10.4.2 Additions to the Domestic Substances List

When the period for assessment has expired, Environment Canada is obliged under section 87(1) of the CEPA, 1999 to add a substance to the DSL and, if it appears on the NDSL, delete it from that list, within 120 days after the following conditions are met:

(a) Environment Canada has been provided with the information prescribed in section 81 or 82 of the CEPA, 1999 and any additional information or test results required under subsection 84(1) of the CEPA, 1999. Because inclusion of a substance on the DSL may permit unrestricted use if there is not a SNAc, any substance for which the full complement of information requirements (i.e., Schedules II, III, VI, VII or VIII) were reduced as a result of limited use or exposure, or for which waivers were granted under paragraph 81(8)(b), may not have satisfied this criterion;

(b) Environment Canada is satisfied that the substance has been imported or manufactured in excess of:

   (1) 5 000 kg in any calendar year or an accumulated total of 25 000 kg for chemicals/biochemicals listed on the NDSL;

   (2) 10 000 kg in any calendar year or an accumulated total of 50 000 kg for chemicals/biochemicals not listed on the NDSL;

(3) 5 000 kg in any calendar year or an accumulated total of 25 000 kg for transitional chemicals/biochemicals, provided that the notifier has submitted a Schedule II notification within five years after the New Substances Notification Regulations are in force; or

(4) 1 000 kg in any calendar year or an accumulated total of 5 000 kg for polymers/biopolymers not listed on the NDSL but manufactured solely from reactants listed on the DSL or NDSL , and 10 000 kg in any calendar year or an accumulated total of 50 000 kg for all other polymers/biopolymers; and

(c) no conditions have been imposed on the substance under paragraph 84(1)(a) of CEPA, 1999.

When the period for assessment has expired, Environment Canada is obliged under subsection 87(5) of the CEPA, 1999 to add a substance to the DSL and, if it appears on the NDSL, delete it from that List, within 120 days after the following conditions are met:

(a) Environment Canada has been provided with any information in respect of the substance under subsections 81(1) to (13) or section 82 of the CEPA, 1999, any additional information or test results required under subsection 84(1), and any other prescribed information;

(b) no conditions specified under paragraph 84(1)(a) in respect of the substance remain in effect.

Please note that an amendment to the NSNR must be in place for a substance to be added to the DSL pursuant to subsection 87(5) of the CEPA, 1999.

Substances that are not anticipated to pose a risk to the environment and human health, regardless of their use or quantity, will be placed on the DSL without restrictions. Substances that were suspected of being toxic or capable of becoming toxic in the assessment can only be placed on the DSL if they are controlled under section 93 of the CEPA, 1999.

10.5 Program Overview

A schematic overview of the New Substances Notification assessment process is shown in Figure 9.

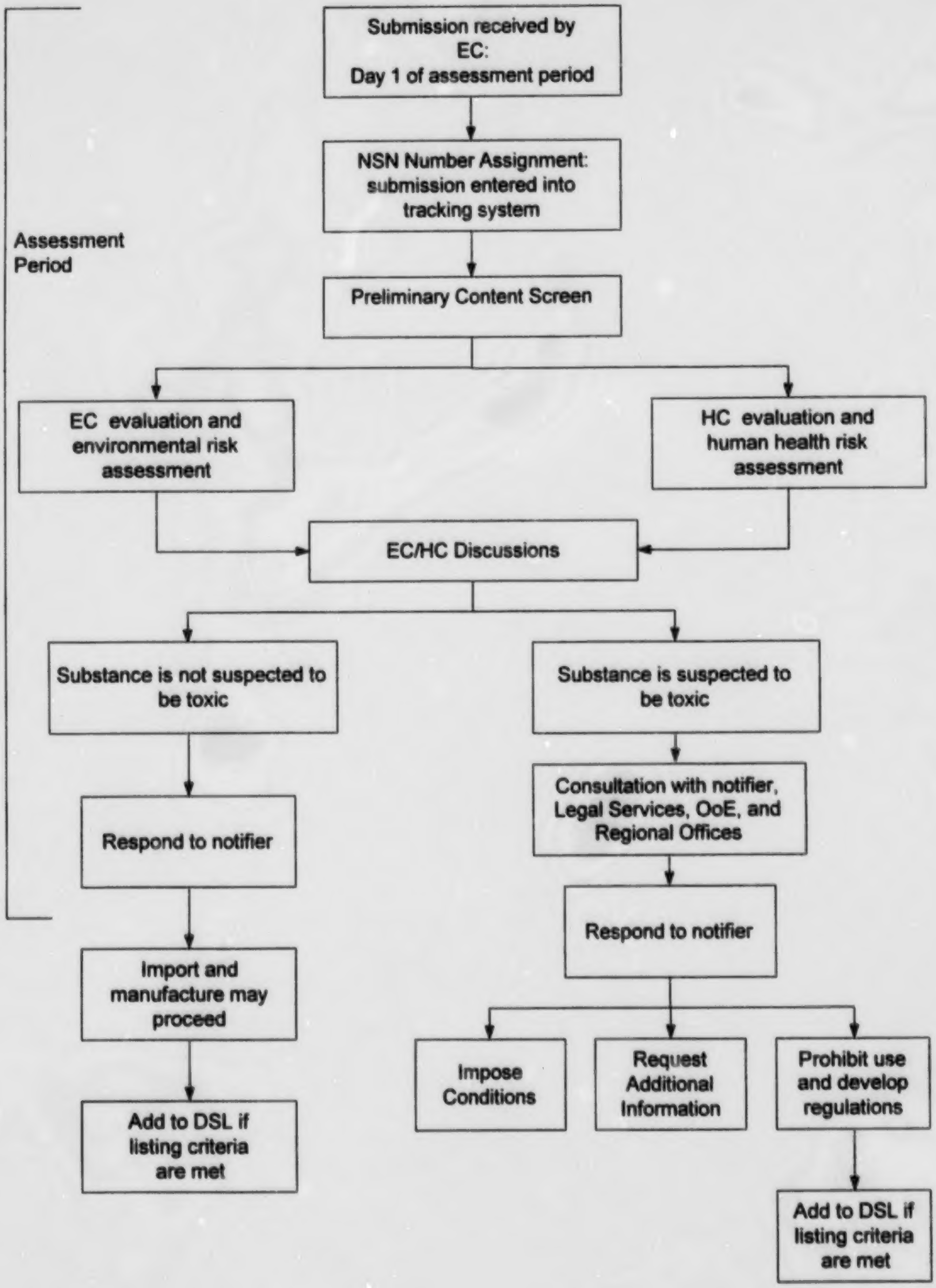
Submission received by EC: Day 1 of assessment period
NSN Number Assignment: submission entered into tracking system
Assessment Period
Preliminary Content Screen
EC evaluation and environmental risk assessment
HC evaluation and human health risk assessment
EC/HC Discussions
Substance is not suspected to be toxic
Substance is suspected to be toxic
Respond to notifier
Consultation with notifier, Legal Services, OoE, and Regional Offices
Import and manufacture may proceed
Respond to notifier
Impose Conditions
Request Additional Information
Prohibit use and develop regulations
Add to DSL if listing criteria are met
Add to DSL if listing criteria are met

Figure 9 **Overview of New Substances Notification Assessment Process**

Section 11 - Post-notification Responsibilities

11.1 Correction of Information

Any person who has submitted information in support of a notification and later finds that the information is erroneous must immediately notify Environment Canada of that fact and submit the necessary correction.

This requirement relates only to information that existed at the time of the notification. Information generated after a notification that reasonably supports the conclusion that the substance is toxic[6], or is capable of becoming toxic, must be provided to Environment Canada under the provisions of Section 70 of the CEPA, 1999 (see Section 11.3).

11.2 Notice of Excess Quantity

After proceeding with the import or manufacture of the substance, subsection 81(14) of the CEPA, 1999 requires notifiers to advise Environment Canada when the manufactured or imported quantity exceeds:

(a) 5 000 kg in any calendar year or an accumulated total of 25 000 kg for chemicals/biochemicals listed on the NDSL; or

(b) 10 000 kg in any calendar year or an accumulated total of 50 000 kg for chemicals/biochemicals not listed on the NDSL; or

(c) 5 000 kg in any calendar year or an accumulated total of 25 000 kg for transitional chemicals/biochemicals provided these quantities are exceeded after the New Substances Notification Regulations come into force and a Schedule II was provided prior to the appropriate prescribed date (a notice of exceedance under subsection 81(14) is not required for transitional substances that exceeded the above quantities prior to the New Substances Notification Regulations coming into force).

(d) 1 000 kg in any calendar year or an accumulated total of 5 000 kg for polymers/biopolymers not listed on the NDSL but manufactured solely from reactants listed on the DSL or NDSL , and 10 000 kg in any calendar year or an accumulated total of 50 000 kg for all other polymers/biopolymers;

Notification that any of the above prescribed quantities has been exceeded must be provided, within 30 days of exceeding the quantity, to:

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[6] The term "toxic" refers to the interpretation in Section 64 of CEPA and is described in Subsection 10.3.2 of these Guidelines.

New Substances Branch
Environmental Protection Services
Environment Canada
14th Floor, Place Vincent Massey
Ottawa, Ontario K1A 0H3
Canada

This notice will oblige Environment Canada to add the substance to the DSL if all of the criteria described in section 87(1) of the CEPA, 1999 have been met (refer to Subsection 10.4.2 of these Guidelines).

11.3 Section 70 of the Canadian Environmental Protection Act, 1999

If, subsequent to the notification of a new substance, a notifier obtains new information that reasonably supports the conclusion that the substance is toxic, or is capable of becoming toxic, the notifier is obliged under section 70 of the CEPA, 1999 to provide that information to Environment Canada without delay. This information must be provided unless the notifier has actual knowledge that Environment Canada already has the information.

There may be instances when a section 70 notice has been provided on a substance that is subsequently the subject of a New Substances Notification. In these cases, the notifier has the option of either resubmitting this information or referencing the section 70 correspondence containing the submission.

Procedures and criteria for submitting a section 70 notice are described in the guidelines for section 70 of the CEPA, 1999.

Appendix 1 - Schedules of Information under the NSNR

SCHEDULE I

(Paragraphs 6(1)(a) and (2)(a), 8(2)(a), 10(1)(a) and (2)(a), and 10.1(1)(a), subsections 11(3) and 12(2), paragraphs 13(1)(a), 14(1)(a) and 14.1(1)(a) and section 15.1)

INFORMATION REQUIRED IN RESPECT OF SUBSTANCES OTHER THAN PRODUCT DEVELOPMENT SUBSTANCES, SITE-LIMITED INTERMEDIATE SUBSTANCES AND SUBSTANCES MANUFACTURED OR IMPORTED FOR EXPORT ONLY

1. (1) The chemical name of the substance, established in accordance with the chemical nomenclature rules of the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service.

(2) The trade names of the substance and the synonyms of its chemical name, if known.

(3) The Chemical Abstracts Service registry number of the substance, if such a number has been assigned.

(4) A material safety data sheet, as defined in subsection 11(1) of the *Hazardous Products Act*, in respect of the substance, if available.

2. All information in respect of the substance that is relevant to identifying hazards to human health and the environment and that is in the person's possession.

3. The intended uses of the substance.

4. The identification of other government agencies, either abroad or within Canada, that the person has notified of the manufacture or importation of the substance, and the purpose of such notification.

SCHEDULE II

(Paragraphs 6(1)(b) and (2)(b), subsection 6(3), paragraph 6(4)(a), subsections 6(5) and (6), paragraphs 8(1)(a) and (2)(b)and 10.1(1)(b), subsections 11(3), 12(2) and 13(1), paragraph 14.1(1)(b) and section 15.1)

INFORMATION REQUIRED IN RESPECT OF SUBSTANCES OTHER THAN PRODUCT DEVELOPMENT SUBSTANCES, SITE-LIMITED INTERMEDIATE SUBSTANCES AND SUBSTANCES MANUFACTURED OR IMPORTED FOR EXPORT ONLY

1. (1) The chemical name of the substance, established in accordance with the chemical nomenclature rules of the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service.

(2) The trade names of the substance and the synonyms of its chemical name, if known.

(3) The Chemical Abstracts Service registry number of the substance, if such a number can be assigned.

(4) The following identification information in respect of the substance:

(a) its structural formula;

(b) its gram molecular weight;

(c) the degree of purity in its technical grade composition, if applicable;

(d) any known impurities present and their concentration by weight; and

(e) any additives and stabilizers that are essential for the purposes of marketing the substance, and their concentrations by weight.

(5) A material safety data sheet, as defined in subsection 11(1) of the *Hazardous Products Act*, in respect of the substance, if available.

2. (1) The following physical and chemical data in respect of the substance:

(a) its melting point or the temperature at which it decomposes

(i) expressed in degrees Celsius, where its melting point or the temperature at which it decomposes is -50 °C or greater but not greater than 300 °C, and

(ii) in any other case, expressed as "less than -50 °C" or "greater than 300 °C", as appropriate;

(b) its boiling point or the temperature at which it decomposes

(i) expressed in degrees Celsius, where its boiling point or the temperature at which it decomposes is -50 °C or greater but not greater than 300 °C, and

(ii) in any other case, expressed as "less than -50 °C" or "greater than 300 °C", as appropriate;

(c) its density;

(d) its vapour pressure, if it has a standard boiling point of 0 °C or greater;

(e) its water solubility;

(f) its octanol-water partition coefficient, if its solubility in water is 10^{-6} g/L or greater;

(g) one of an infra-red, ultra-violet, mass or nuclear magnetic resonance spectrum suitable for characterization of the substance;

(h) its dissociation constants;

(i) adsorption-desorption screening test data;

(j) its hydrolysis rate as a function of pH and, if known, an identification of the products of the hydrolysis;

(k) if the substance is a solid at room temperature and its water solubility is less than 10^{-6} g/L, particle size or fibre length distribution data, if applicable; and

(l) its fat solubility, if its solubility in water is less than 10^{-6} g/L.

(2) Data from the most appropriate type of acute mammalian toxicity test of the substance, namely oral, dermal or inhalation, selected on the basis of the most significant route of potential human exposure to the substance.

(3) For a test referred to in sub-item (2), the following information:

(a) the age, sex, number, species, strain and source of the animals tested;

SCHEDULE II - *Concluded*

(b) the route by which the substance is administered and the conditions under which the test is conducted; and

(c) the dose of the substance, the vehicle by means of which the substance is administered and the concentration of the substance in the vehicle.

(4) Mutagenicity data obtained from one *in vitro* test of the substance, with and without metabolic activation, for chromosomal aberrations or gene mutations or another indicator of mutagenicity that permits an assessment of *in vitro* mutagenicity.

(5) All other information and test data in respect of the substance that are relevant to identifying hazards to human health and the environment and that are in the person's possession or to which the person ought reasonably to have access.

(6) A description or specification of the test procedures followed in developing the test data, including, for data developed on or after July 1, 1994 or for test procedures that are not prescribed, test methods, reference substances and quality control and quality assurance procedures.

(7) Notwithstanding subitem (6), in the case of a biotechnology product that is not derived from whole animals or whole plants, a description or specification of the test procedures followed in developing the test data, including, for data developed on or after September 1, 1997, or for test procedures that are not prescribed, test methods, reference substances and quality control and quality assurance procedures.

3. (1) Manufacture, importation, use and disposal information, including an estimate of the quantity of the substance to be manufactured and imported annually, its intended uses, the methods recommended for its destruction or disposal and the expected transportation modes for its distribution.

(2) Recommended precautions and emergency measures, including personal protective equipment to be used, engineering controls, leak and spill clean-up procedures, handling procedures, storage requirements and first-aid measures.

(3) The anticipated nature and extent of the substance's release into the environment.

(4) The estimated number of persons who may become exposed to the substance.

4. The identification of other government agencies, either abroad or within Canada, that the person has notified of the manufacture or importation of the substance, and the purpose of such notification.

SCHEDULE III

(Paragraphs 6(1)(c) and (4)(b), subsection 6(6), paragraphs 8(1)(b) and 10.1(b) and subsections 11(3) and 12(2))

INFORMATION REQUIRED IN RESPECT OF SUBSTANCES OTHER THAN PRODUCT DEVELOPMENT SUBSTANCES, SITE-LIMITED INTERMEDIATE SUBSTANCES AND SUBSTANCES MANUFACTURED OR IMPORTED FOR EXPORT ONLY

1. (1) The chemical name of the substance, established in accordance with the chemical nomenclature rules of the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service.

(2) The trade names of the substance and the synonyms of its chemical name, if known.

(3) The Chemical Abstracts Service registry number of the substance, if such a number can be assigned.

(4) The following identification information in respect of the substance:

(a) its structural formula;

(b) its gram molecular weight;

(c) the degree of purity in its technical grade composition, if applicable;

(d) known impurities present and their concentration by weight; and

(e) any additives and stabilizers that are essential for the purposes of marketing the substance, and their concentrations by weight.

(5) A material safety data sheet, as defined in subsection 11(1) of the *Hazardous Products Act*, in respect of the substance, if available.

2. (1) The following physical and chemical data in respect of the substance:

(a) its melting point or the temperature at which it decomposes

(i) expressed in degrees Celsius, where its melting point or the temperature at which it decomposes is -50 °C or greater but not greater than 300 °C, and

(ii) in any other case, expressed as "less than -50 °C" or "greater than 300 °C", as appropriate;

SCHEDULE III - *Continued*

(b) its boiling point or the temperature at which it decomposes

(i) expressed in degrees Celsius, where its boiling point or the temperature at which it decomposes is -50 °C or greater but not greater than 300 °C, and

(ii) in any other case, expressed as "less than -50 °C" or "greater than 300 °C", as appropriate;

(c) its density;

(d) its vapour pressure, if it has a standard boiling point of 0 °C or greater;

(e) its water solubility;

(f) its octanol-water partition coefficient, if its solubility in water is 10^{-6} g/L or greater;

(g) one of an infra-red, ultra-violet, mass or nuclear magnetic resonance spectrum suitable for characterization of the substance;

(h) its dissociation constants;

(i) adsorption-desorption screening test data;

(j) its hydrolysis rate as a function of pH and, if known, an identification of the products of the hydrolysis;

(k) if the substance is a solid at room temperature and its water solubility is less than 10^{-6} g/L, particle size or fibre length distribution data, if applicable; and

(l) its fat solubility.

(2) Data from the two most appropriate types of acute mammalian toxicity tests of the substance, namely, oral, dermal or inhalation, selected on the basis of the two most significant routes of potential human exposure to the substance.

(3) Data from one skin irritation test and one skin sensitization test of the substance.

(4) Data from one repeated dose mammalian toxicity test of the substance of at least 28 days duration, or of at least 14 days duration where it can be demonstrated that the data were obtained on or before July 1, 1994, which test is selected on the basis of the most significant route of potential human exposure to the substance.

SCHEDULE III - *Continued*

(4.1) Notwithstanding subitem (4), in the case of a biotechnology product that is not derived from whole animals or whole plants, data from one repeated dose mammalian toxicity test of the biotechnology product of at least 28 days duration, or of at least 14 days duration where it can be demonstrated that the data were obtained before September 1, 1997, which test is selected on the basis of the most significant route of potential human exposure to the biotechnology product.

(5) For the tests referred to in sub-items (2) to (4), the following information:

(a) the age, sex, number, species, strain and source of the animals tested;

(b) the route by which the substance is administered and the conditions under which the test is conducted; and

(c) the dose of the substance, the vehicle by means of which the substance is administered and the concentration of the substance in the vehicle.

(6) Mutagenicity data obtained from the following tests of the substance:

(a) one *in vitro* test, with and without metabolic activation, for gene mutations;

(b) one *in vitro* test, with and without metabolic activation, for chromosomal aberrations in mammalian cells; and

(c) one *in vivo* mammalian test for chromosomal aberrations or gene mutations or another indicator of mutagenicity that, together with evidence that the tissue investigated was exposed to the substance or its metabolites, permits an assessment of *in vivo* mutagenicity.

(7) Fish and daphnia acute toxicity test data in respect of the substance, including, as appropriate, limit test results or LC_{50} results.

(8) Ready biodegradability test data in respect of the substance and, if known, identification of the products of biodegradation.

(9) All other information and test data in respect of the substance that are relevant to identifying hazards to human health and the environment and that are in the person's possession or to which the person ought reasonably to have access.

(10) A description or specification of test procedures followed in developing the test data, including, for data developed after July 1, 1994 or for test procedures that are not prescribed, test methods, reference substances and quality control and quality assurance procedures.

SCHEDULE III - *Concluded*

(11) Notwithstanding subitem (10), in the case of a biotechnology product that is not derived from whole animals or whole plants, a description or specification of the test procedures followed in developing the test data, including, for data developed on or after September 1, 1997, or for test procedures that are not prescribed, test methods, reference substances and quality control and quality assurance procedures.

3. (1) Manufacture, importation, use and disposal information, including an estimate of the quantity of the substance to be manufactured and imported annually, its intended uses, the methods recommended for its destruction or disposal and the expected transportation modes for its distribution.

(2) Recommended precautions and emergency measures, including personal protective equipment to be used, engineering controls, leak and spill clean-up procedures, handling procedures, storage requirements and first-aid measures.

(3) The anticipated nature and extent of the substance's release into the environment.

(4) The estimated number of persons who may become exposed to the substance.

4. Full descriptions of or specific reference to analytical test methods that can be used for the detection and determination of concentrations of the substance at or below the limit test results or the LC_{50} results provided under sub-item 2(7).

5. The identification of other government agencies, either abroad or within Canada, that the person has notified of the manufacture or importation of the substance, and the purpose of such notification.

SCHEDULE IV

(Section 8, paragraph 10.1(1)(c) and subsections 11(3) and 12(2))

INFORMATION REQUIRED IN RESPECT OF PRODUCT DEVELOPMENT SUBSTANCES

1. (1) The chemical name of the product development substance established in accordance with the chemical nomenclature rules of the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service.

(2) The Chemical Abstracts Service registry number of the product development substance, if known.

2. The following identification information in respect of the product development substance:

(a) its structural formula;

(b) its gram molecular weight;

(c) its degree of purity; and

(d) any known impurities present and their concentration by weight.

3. All information and test data in respect of the product development substance that are relevant to identifying hazards to human health and the environment and that are in the person's possession or to which the person ought reasonably to have access.

4. (1) A description of the plan for product development including the following information in respect of the product development substance:

(a) the manufacturing and import activities;

(b) its storage;

(c) its transport;

(d) its intended uses;

(e) an assessment of the potential for its release into the environment or for persons to be exposed to it, and any measures that will be taken to protect against such release or exposure;

(f) the environmental fate; and

SCHEDULE IV - *Concluded*

(g) analytical test methods that detect the product development substance in the environment and that are in the person's possession or to which the person ought reasonably to have access.

(2) A complete description of the plan for disposing of the product development substance outlining

(a) all products in which the product development substance will be used;

(b) the plan for recalling, recapturing and disposing of the product development substance; and

(c) the ultimate mass balance of the product development substance based on the quantity produced and its disposition.

SCHEDULE V

(Paragraphs 10(1)(b) and (2)(b), subsections 10(3) and (4), paragraph 10.1(1)(b), subsections 11(3) and 12(2), paragraph 14(1)(b), subsection 14(3), paragraph 14.1(1)(b) and section 15.1)

INFORMATION REQUIRED IN RESPECT OF SITE-LIMITED INTERMEDIATE SUBSTANCES AND SUBSTANCES MANUFACTURED OR IMPORTED FOR EXPORT ONLY

1. (1) The chemical name of the site-limited intermediate substance or substance for export only, established in accordance with the chemical nomenclature rules of the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service.

(2) The trade names of the site-limited intermediate substance or substance for export only and the synonyms of its chemical name, if known.

(3) The Chemical Abstracts Service registry number of the site-limited intermediate substance or substance for export only, if such a number has been assigned.

(4) A material safety data sheet, as defined in subsection 11(1) of the *Hazardous Products Act*, in respect of the site-limited intermediate substance or substance for export only, if available.

2. (1) All information and test data in respect of the site-limited intermediate substance or substance for export only that are relevant to identifying hazards to human health and the environment and that are in the person's possession or to which the person ought reasonably to have access.

(2) A description or specification of the test procedures followed in developing the test data, including, for data developed on or after July 1, 1994 or for test procedures that are not prescribed, test methods, reference substances and quality control and quality assurance procedures.

(3) Notwithstanding subitem (2), in the case of a biotechnology product that is not derived from whole animals or whole plants, a description or specification of the test procedures followed in developing the test data, including, for data developed on or after September 1, 1997, or for test procedures that are not prescribed, test methods, reference substances and quality control and quality assurance procedures.

3. Data from environmental degradation tests including hydrolysis rate as a function of pH and ready biodegradability and, if known, an identification of the products of the hydrolysis and biodegradation.

SCHEDULE V - *Concluded*

4. Data from the most appropriate type of acute mammalian toxicity test, namely, oral, dermal or inhalation, selected on the basis of the most significant route of potential human exposure to the substance.

5. A description of the manufacturing and import activities in respect of the substance, information in respect of its storage, transport and uses, the potential for its release into the environment or for persons to be exposed to it, any measures that will be taken to protect agains such release or exposure and the environmental fate.

6. The identification of other government agencies, either abroad or within Canada, that the person has notified of the manufacture or importation of the substance and the purpose of such notification.

SCHEDULE VI

(Subparagraphs 18(1)(a)(i) and 19(2)(a)(i), paragraph 19(2)(b), subsections 19(3) and 23(1), paragraphs 23(3)(b) and 23.1(1)(a), subsections 24(3) and 25(2), clause 26(1)(a)(i)(A), paragraph 26(2)(a), subparagraph 26(2)(b)(ii), paragraphs 27(1)(b) and 27.1(1)(a) and section 28.1)

INFORMATION REQUIRED IN RESPECT OF POLYMERS OTHER THAN PRODUCT DEVELOPMENT SUBSTANCES, SITE-LIMITED INTERMEDIATE SUBSTANCES AND SUBSTANCES MANUFACTURED OR IMPORTED FOR EXPORT ONLY

1. (1) The chemical name of the polymer, established in accordance with the chemical nomenclature rules of the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service.

(2) The trade names of the polymer and the synonyms of its chemical name, if known.

(3) The Chemical Abstracts Service registry number of the polymer, if such a number can be assigned.

(4) The molecular formula of the polymer, if possible.

(5) The structural formula of the polymer, if possible, or else a partial structural formula.

(6) The composition of the polymer, including constituents such as monomers, other reactants, known impurities expressed in per cent by weight and additives that are essential for the purpose of marketing.

(7) A material safety data sheet, as defined in subsection 11(1) of the *Hazardous Products Act*, in respect of the polymer, if available.

2. (1) The following physical and chemical data in respect of the polymer:

(a) its number average molecular weight;

(b) the maximum concentration, in per cent, of all constituents with molecular weights of less than 500 daltons and all constituents with molecular weights of less than 1 000 daltons; and

(c) its physical state.

(2) All other information and test data in respect of the polymer that are relevant to identifying hazards to human health and the environment and that are in the person's possession or to which the person ought reasonably to have access.

Schedule VI - *Concluded*

(3) A description or specification of the test procedures followed in developing the test data, including, for data developed on or after July 1, 1994 or for test procedures that are not prescribed, test methods, reference substances and quality control and quality assurance procedures.

(4) Notwithstanding subitem (3), in the case of a biotechnology product that is not derived from whole animals or whole plants, a description or specification of the test procedures followed in developing the test data, including, for data developed on or after September 1, 1997, or for test procedures that are not prescribed, test methods, reference substances and quality control and quality assurance procedures.

3. (1) Manufacture, importation, use and disposal information, including an estimate of the quantity of the polymer to be manufactured and imported annually, its intended uses, the methods recommended for its destruction or disposal and the expected transportation modes for its distribution.

(2) Recommended precautions and emergency measures, including personal protective equipment to be used, engineering controls, leak and spill clean-up procedures, handling procedures, storage requirements and first-aid measures.

4. The identification of other government agencies, either abroad or within Canada, that the person has notified of the manufacture or importation of the polymer, and the purpose of such notification.

SCHEDULE VII

(Paragraph 18(1)(b), subsections 18(2) and (3), clause 19(2)(b)(ii)(B), paragraphs 23(3)(a) and 23.1(1)(b), subsections 24(3) and 25(2), clause 26(1)(a)(i)(B), paragraphs 26(1)(b), 27(1)(a) and 27.1(1)(b) and section 28.1)

INFORMATION REQUIRED IN RESPECT OF POLYMERS OTHER THAN PRODUCT DEVELOPMENT SUBSTANCES, SITE-LIMITED INTERMEDIATE SUBSTANCES AND SUBSTANCES MANUFACTURED OR IMPORTED FOR EXPORT ONLY

1. (1) The chemical name of the polymer, established in accordance with the chemical nomenclature rules of the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service.

(2) The trade names of the polymer and the synonyms of its chemical name, if known.

(3) The Chemical Abstracts Service registry number of the polymer, if such a number can be assigned.

(4) The molecular formula of the polymer, if possible.

(5) The structural formula of the polymer, if possible, or else a partial structural formula.

(6) The composition of the polymer, including constituents such as monomers, other reactants, known impurities expressed in per cent by weight and essential additives for the purpose of marketing.

(7) A material safety data sheet, as defined in subsection 11(1) of the *Hazardous Products Act*, in respect of the polymer, if available.

2. (1) The following physical and chemical data in respect of the polymer:

(a) its number average molecular weight;

(b) the maximum concentration, in per cent, of all residual constituents with molecular weights of less than 500 daltons and all residual constituents with molecular weights of less than 1 000 daltons;

(c) its physical state;

(d) whether it is formulated for dispersal in water;

(e) its solubility in water at pH 7

SCHEDULE VII - *Continued*

(i) expressed in milligrams per litre, where its solubility is 10 mg/L or greater, and

(ii) expressed as "less than 10 mg/L", where its solubility is less than 10 mg/L;

(f) its solubility in n-octanol or its octanol-water partition coefficient expressed, for solubility in n-octanol,

(i) in milligrams per litre, where its solubility is 50 mg/L or greater, and

(ii) as "less than 50 mg/L", where its solubility is less than 50 mg/L; and

(g) its solubility in water at pH 1 and pH 10, where its solubility is 50 mg/L or greater.

(2) Data from one acute lethal toxicity test with one representative species of fish or daphnia for the water-soluble portion of the polymer, where its solubility in water is 10 mg/L or greater.

(3) In respect of a cationic polymer or a polymer expected to become cationic in the aquatic environment, data from

(a) one aquatic acute lethal toxicity test, other than a test referred to in sub-item (2), with one representative species of fish or daphnia; and

(b) one ready biodegradability test for the water-soluble portion of the polymer, where its solubility in water is 50 mg/L or greater.

(4) In respect of an anionic polymer, data from tests on freshwater green algae.

(5) Data from one acute mammalian oral toxicity test of the polymer.

(6) For the test referred to in sub-item (5), the following information:

(a) the age, sex, number, species, strain and source of the animals tested;

(b) the conditions under which the test is conducted; and

(c) the dose of the polymer, the vehicle by means of which the polymer is administered and the concentration of the polymer in the vehicle.

SCHEDULE VII - *Concluded*

(7) All other information and test data in respect of the polymer that are relevant to identifying hazards to human health and the environment and that are in the person's possession or to which the person ought reasonably to have access.

(8) A description or specification of the test procedures followed in developing the test data, including, for data developed on or after July 1, 1994 or for test procedures that are not prescribed, test methods, reference substances and quality control and quality assurance procedures.

(9) Notwithstanding subitem (8), in the case of a biotechnology product that is not derived from whole animals or whole plants, a description or specification of the test procedures followed in developing the test data, including, for data developed on or after September 1, 1997, or for test procedures that are not prescribed, test methods, reference substances and quality control and quality assurance procedures.

3. (1) Manufacture, importation, use and disposal information, including an estimate of the quantity of the polymer to be manufactured and imported annually, its intended uses, the methods recommended for its destruction or disposal and the expected transportation modes for its distribution.

(2) Recommended precautions and emergency measures, including personal protective equipment to be used, engineering controls, leak and spill clean-up procedures, handling procedures, storage requirements and first-aid measures.

(3) The anticipated nature and extent of the polymer's release into the environment.

(4) The estimated number of persons who may become exposed to the polymer.

4. The identification of other government agencies, either abroad or within Canada, that the person has notified of the manufacture or importation of the polymer, and the purpose of such notification.

SCHEDULE VIII

(Clauses 18(1)(b)(ii)(B) and (2)(b)(ii)(B), paragraph 23.1(1)(b) and subsections 24(3) and 25(2))

INFORMATION REQUIRED IN RESPECT OF POLYMERS OTHER THAN PRODUCT DEVELOPMENT SUBSTANCES, SITE-LIMITED INTERMEDIATE SUBSTANCES AND SUBSTANCES MANUFACTURED OR IMPORTED FOR EXPORT ONLY

1. (1) The chemical name of the polymer, established in accordance with the chemical nomenclature rules of the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service.

(2) The trade names of the polymer and the synonyms of its chemical name, if known.

(3) The Chemical Abstracts Service registry number of the polymer, if such a number can be assigned.

(4) The molecular formula of the polymer, if possible.

(5) The structural formula of the polymer, if possible, or else a partial structural formula.

(6) The composition of the polymer, including constituents such as monomers, other reactants, known impurities expressed in per cent by weight and essential additives for the purpose of marketing.

(7) A material safety data sheet, as defined in subsection 11(1) of the *Hazardous Products Act*, in respect of the polymer, if available.

2. (1) The following physical and chemical data in respect of the polymer:

(a) its number average molecular weight;

(b) the maximum concentrations, in per cent, of all residual constituents with molecular weights of less than 500 daltons and of all residual constituents with molecular weights of less than 1 000 daltons;

(c) its physical state;

(d) whether it is formulated for dispersal in water;

(e) its solubility in water at pH 7

SCHEDULE VIII - *Continued*

(i) expressed in milligrams per litre, where its solubility is 10 mg/L or greater, and

(ii) expressed as "less than 10 mg/L", where its solubility is less than 10 mg/L;

(f) its solubility in n-octanol or the octanol-water partition coefficient expressed, for solubility in n-octanol,

(i) in milligrams per litre, where its solubility is 50 mg/L or greater, and

(ii) as "less than 50 mg/L", where its solubility is less than 50 mg/L;

(g) its solubility in water at pH 1 and pH 10, where its solubility is 50 mg/L or greater;

(h) one ultra-violet spectrum; and

(i) its hydrolysis rate as a function of pH where its solubility in water is 50 mg/L or greater and, if known, an identification of the products of the hydrolysis.

(2) Data from one acute lethal toxicity test with one representative species of fish or daphnia for the water-soluble portion of the polymer, where its solubility in water is 10 mg/L or greater.

(3) Data from one ready biodegradability test on the water-soluble portion of the polymer, where its solubility in water is 50 mg/L or greater.

(4) In respect of a cationic polymer or a polymer expected to become cationic in the aquatic environment, data from one aquatic acute lethal toxicity test, other than a test referred to in sub-item (2), with one representative species of fish or daphnia.

(5) In respect of an anionic polymer, data from tests on freshwater green algae.

(6) Data from one acute mammalian oral toxicity test of the polymer.

(7) Data from one skin irritation test and one skin sensitization test of the polymer.

(8) Data from one repeated dose mammalian toxicity test of the polymer of at least 28 days duration, or of at least 14 days duration where it can be demonstrated that the data were obtained before July 1, 1994, which test is selected on the basis of the most significant route of potential human exposure.

SCHEDULE VIII - *Continued*

(8.1) Notwithstanding subitem (8), in the case of a biotechnology product that is not derived from whole animals or whole plants, data from one repeated dose mammalian toxicity test of the biotechnology product of at least 28 days duration, or of at least 14 days duration where it can be demonstrated that the data were obtained before September 1, 1997, which test is selected on the basis of the most significant route of potential human exposure to the biotechnology product.

(9) For the tests referred to in sub-items (6) to (8), the following information:

(a) the age, sex, number, species, strain and source of the animals tested;

(b) the route by which the polymer is administered and the conditions under which the test is conducted; and

(c) the dose of the polymer, the vehicle by means of which the polymer is administered and the concentration of the polymer in the vehicle.

(10) Mutagenicity data obtained from the following tests of the polymer:

(a) one *in vitro* test, with and without metabolic activation, for gene mutations;

(b) one *in vitro* test, with and without metabolic activation, for chromosomal aberrations in mammalian cells; and

(c) one *in vivo* mammalian test for chromosomal aberrations or gene mutations or another indicator of mutagenicity that, together with evidence that the tissue investigated was exposed to the polymer or its metabolites, permits an assessment of *in vivo* mutagenicity.

(11) All other information and test data in respect of the polymer that are relevant to identifying hazards to human health and the environment and that are in the person's possession or to which the person ought reasonably to have access.

(12) A description or specification of the test procedures followed in developing the test data, including, for data developed on or after July 1, 1994 or for test procedures that are not prescribed, test methods, reference substances and quality control and quality assurance procedures.

(13) Notwithstanding subitem (12), in the case of a biotechnology product that is not derived from whole animals or whole plants, a description or specification of the test procedures followed in developing the test data, including, for data developed on or after September 1, 1997, or for test procedures that are not prescribed, test methods, reference substances and quality control and quality assurance procedures.

SCHEDULE VIII - *Concluded*

3. (1) Manufacture, importation, use and disposal information, including an estimate of the quantity of the polymer to be manufactured and imported annually, its intended uses, the methods recommended for its destruction or disposal and the expected transportation modes for its distribution.

(2) Recommended precautions and emergency measures, including personal protective equipment to be used, engineering controls, leak and spill clean-up procedures, handling procedures, storage requirements and first-aid measures.

(3) The anticipated nature and extent of the polymer's release into the environment.

(4) The estimated number of persons who may become exposed to the polymer.

4. The identification of other government agencies, either abroad or within Canada, that the person has notified of the manufacture or importation of the polymer, and the purpose of such notification.

SCHEDULE IX

(Paragraphs 19(1)(a) and (b))

TYPES OF POLYMERS

1. A cationic polymer or a polymer that is reasonably expected to become cationic in a natural environment, except

   (a) a polymer that has a combined equivalent weight for the cationic group in the polymer greater than 5, 000; or

   (b) a polymer that is a solid material, that is not soluble or dispersible in water and that will be used only in the solid phase, such as polymers that can be used as ion exchange beads.

2. A polymer that is designed, or can be expected, to substantially degrade, decompose or depolymerize, including polymers that could substantially decompose after manufacture and use, even though they are not actually intended to do so. Degradation, decomposition or depolymerization mean the types of chemical changes that convert a polymeric substance into simpler, smaller substances, through processes including but not limited to oxidation, hydrolysis, attack by solvents, heat, light or microbial action.

3. A polymer that contains as an integral part of its composition only one or none of the following atomic elements: carbon, hydrogen, nitrogen, oxygen, silicon and sulphur.

4. A polymer that contains

   (a) any atomic elements other than carbon, hydrogen, nitrogen, oxygen, silicon, sulphur, fluorine, chlorine, bromine or iodine covalently bound to carbon;

   (b) any monatomic counterions other than chlorine ion, bromine ion, iodine ion, sodium ion, divalent magnesium, trivalent aluminum, potassium ion or divalent calcium; and

   (c) 0.2% or more by weight of any atomic element or combination of the following atomic elements: lithium, boron, phosphorus, titanium, manganese, iron, nickel, copper, zinc, tin or zirconium.

5. A polymer

   (a) that contains reactive functional groups, other than carboxylic acid groups, aliphatic hydroxyl groups, unconjugated olefinic groups that are considered

SCHEDULE IX - *Concluded*

"ordinary"[7], butenedioic acid groups, blocked isocyanates including ketoxime-blocked isocyanates, thiols, unconjugated nitrile groups, halogens excluding reactive halogen-containing groups such as benzylic or allylic halides, and conjugated olefinic groups contained in naturally occurring fats, oils and carboxylic acids, in combined equivalent weights of less than 5, 000; or

(b) in which the only reactive functional groups present are part of acid halides, acid anhydrides, aldehydes, hemiacetals, methylol-amides, methylol-amines, methylol-ureas, alkoxysilanes with alkoxy greater than C_2-alkoxysilanes, allyl ethers, conjugated olefins, cyanates, epoxides, imines, unsubstituted positions ortho or para to phenolic hydroxyl, in combined equivalent weights of less than 1,000.

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[7] Not specially activated either by being part of a larger functional group, such as a vinyl ether, or by other activating influences, for example, strongly electron-withdrawing sulfone group with which the olefinic groups interact.

SCHEDULE X
(Paragraph 19(1)(c))

LIST OF REACTANTS AND THEIR CHEMICAL ABSTRACTS SERVICE REGISTRY NUMBER

Monobasic Acids and Natural Oils

Benzoic acid (65-85-0)
Canola oil (120962-03-0*)
Coconut oil (8001-31-8*)
Corn oil (8001-30-7*)
Cottonseed oil (8001-29-4*)
Dodecanoic acid (143-07-7)
Fatty acids, $C_{16\text{-}18}$ and C_{18}-unsaturated (67701-08-0*)
Fatty acids, castor oil (61789-44-4*)
Fatty acids, coco (61788-47-4*)
Fatty acids, dehydrated castor oil (61789-45-5*)
Fatty acids, linseed oil (68424-45-3*)
Fatty acids, safflower oil (93165-34-5*)
Fatty acids, soyabean oil (68308-53-2*)
Fatty acids, sunflower oil (84625-38-7*)
Fatty acids, sunflower oil, conjugated (68953-27-5*)
Fatty acids, tall-oil (61790-12-3*)
Fatty acids, tall-oil, conjugated *
Fatty acids, vegetable oil (61788-66-7*)
Glycerides, $C_{16\text{-}18}$ and C_{18}-unsaturated (67701-30-8*)
Heptanoic acid (111-14-8)
Hexanoic acid (142-62-1)
Hexanoic acid, 3,3,5-trimethyl (3302-10-1)
Linseed oil (8001-26-1*)
Linseed oil, oxidized (68649-95-6*)
Nonanoic acid (112-05-0)

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* Chemical substance of unknown or vaiable composition, complex reaction products and biological materials (UVCB).

* Chemical substance of unknown or variable composition, complex reaction products and biological materials (UVCB).

SCHEDULE X - *Continued*

Oils, anchovy (128952-11-4*)
Oils, babassu palm (91078-92-1*)
Oils, cannabis*
Oils, herring (68153-06-0*)
Oils, menhaden (8002-50-4*)
Oils, oiticica (8016-35-1*)
Oils, palm kernel (8023-79-8*)
Oils, perilla (68132-21-8*)
Oils, sardine (93334-41-9*)
Oils, walnut (8024-09-7*)
Safflower oil (8001-23-8*)
Soybean oil (8001-22-7*)
Sunflower oil (8001-21-6*)
Tung oil (8001-20-5*)

Dibasic and Tribasic Acids and Esters

1,2-Benzenedicarboxylic acid (88-99-3)
1,3-Benzenedicarboxylic acid (121-91-5)
1,3-Benzenedicarboxylic acid, dimethyl ester (1459-93-4)
1,4-Benzenedicarboxylic acid (100-21-0)
1,4-Benzenedicarboxylic acid, diethyl ester (636-09-9)
1,4-Benzenedicarboxylic acid, dimethyl ester (120-61-6)
1,2,4-Benzenetricarboxylic acid (528-44-9)
Butanedioic acid (110-15-6)
Butanedioic acid, diethyl ester (123-25-1)
Butanedioic acid, dimethyl ester (123-65-0)
2-Butenedioic acid (E) (110-17-8)
Decanedioic acid (111-20-6)
Decanedioic acid, diethyl ester (110-40-7)
Decanedioic acid, dimethyl ester (106-79-6)
Dodecanedioic acid (693-23-2)
Fatty acids, C_{18}-unsaturated, dimers (61788-89-4*)
Heptanedioic acid (111-16-0)
Heptanedioic acid, dimethyl ester (1732-08-7)

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* Chemical substance of unknown or variable composition, complex reaction products and biological materials (UVCB).

SCHEDULE X - *Continued*

Hexanedioic acid (124-04-9)
Hexanedioic acid, diethyl ester (141-28-6)
Hexanedioic acid, dimethyl ester (627-93-0)
Nonanedioic acid (123-99-9)
Nonanedioic acid, diethyl ester (624-17-9)
Nonanedioic acid, dimethyl ester (1732-10-1)
Octanedioic acid (505-48-6)
Octanedioic acid, dimethyl ester (1732-09-8)
Pentanedioic acid (110-94-1)
Pentanedioic acid, diethyl ester (818-38-2)
Pentanedioic acid, dimethyl ester (1119-40-0)
Undecanedioic acid (1852-04-6)

Polyols

1,3-Butanediol (107-88-0)
1,4-Butanediol (110-63-4)
1,4-Cyclohexanedimethanol (105-08-8)
1,2-Ethanediol (107-21-1)
Ethanol, 2,2'-oxybis- (111-46-6)
1,6-Hexanediol (629-11-8)
1,3-Pentanediol, 2,2,4-trimethyl- (144-19-4)
1,2-Propanediol (57-55-6)
1,3-Propanediol, 2,2-bis(hydroxymethyl)- (115-77-5)
1,3-Propanediol, 2,2-dimethyl- (126-30-7)
1,3-Propanediol, 2-ethyl-2-(hydroxymethyl)- (77-99-6)
1,3-Propanediol, 2-(hydroxymethyl)-2-methyl- (77-85-0)
1,3-Propanediol, 2-methyl- (2163-42-0)
1,2,3-Propanetriol (56-81-5)
1,2,3-Propanetriol, homopolymer (25618-55-7)
2-Propen-1-ol, polymer with ethenylbenzene (25119-62-4)

Modifiers

Acetic acid, 2,2'-oxybis- (110-99-6)
1-Butanol (71-36-3)**
Cyclohexanol (108-93-0)
Cyclohexanol, 4,4'-(1-methylethylidene)bis- (80-04-6)
Ethanol, 2-(2-butoxyethoxy)- (112-34-5)

** This substance may not be used in a substance manufactured from fumaric or maleic acid because of potential risks associated with esters, which may be formed by reaction of those reactants.

SCHEDULE X - *Concluded*

1-Hexanol (111-27-3)

Methanol, hydrolysis products with trichlorohexylsilane and trichlorophenylsilane (72318-84-4*)

1-Phenanthrenemethanol, tetradecahydro-1,4a-dimethyl-7-(1-methylethyl)- (13393-93-6)

Phenol, 4,4'-(1-methylethylidene)bis-, polymer with 2,2'-[(1-methylethylidene)bis(4,1-phenyleneoxymethylene)] bis[oxirane] (25036-25-3)

Siloxanes and silicones, dimethyl, diphenyl; polymers with phenyl silsesquioxanes, methoxy-terminated (68440-65-3*)

Siloxanes and silicones, dimethyl, methoxy phenyl; polymers with phenyl silsesquioxanes, methoxy-terminated (68957-04-0*)

Siloxanes and silicones, methyl phenyl, methoxy phenyl; polymers with phenyl silsesquioxanes, methoxy- and phenyl-terminated (68957-06-2*)

Silsesquioxanes, phenyl propyl (68037-90-1*)

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* Chemical substance of unknown or variable composition, complex reaction products and biological materials (UVCB).

SCHEDULE XI

(Subparagraphs 18(1)(a)(ii) and 19(2)(a)(ii), paragraph 23.1(1)(c), subsections 24(3) and 25(2), subparagraphs 26(1)(a)(ii) and (2)(b)(i), paragraph 27.1(1)(c) and section 28.1)

INFORMATION REQUIRED IN RESPECT OF POLYMERS THAT ARE RESEARCH AND DEVELOPMENT SUBSTANCES

1. (1) The chemical name of the polymer, established in accordance with the chemical nomenclature rules of the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service.

(2) The trade names of the polymer and the synonyms of its chemical name, if known.

(3) The Chemical Abstracts Service registry number of the polymer, if such a number has been assigned.

(4) The identification of the reactants and monomers from which the polymer is manufactured.

(5) A material safety data sheet, as defined in subsection 11(1) of the *Hazardous Products Act*, in respect of the polymer, if available.

2. (1) All information in respect of the polymer that is relevant to identifying hazards to human health and the environment and that is in the person's possession.

(2) The physical state of the polymer.

3. A description of the intended research and development activity for which the polymer is to be used and the location of the activity.

SCHEDULE XII

(Paragraphs 21(b) and 23.1(1)(c) and subsections 24(3) and 25(2))

INFORMATION REQUIRED IN RESPECT OF POLYMERS THAT ARE PRODUCT DEVELOPMENT SUBSTANCES

1. (1) The chemical name of the polymer established in accordance with the chemical nomenclature rules of the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service.

(2) The Chemical Abstracts Service registry number of the polymer, if known.

(3) The molecular formula of the polymer, if possible.

(4) The structural formula of the polymer, if possible, or else a partial structural formula.

(5) The composition of the polymer, including monomers, other reactants, additives and impurities of the polymer.

(6) A material safety data sheet, as defined in subsection 11(1) of the *Hazardous Products Act*, in respect of the polymer, if available.

2. The following physical and chemical data in respect of the polymer:

(a) its number average molecular weight;

(b) the maximum concentration, in per cent, of all residual constituents with molecular weights of less than 500 daltons and all residual constituents with molecular weights of less than 1 000 daltons; and

(c) its physical state.

3. (1) All information and test data in respect of the polymer that are relevant to identifying hazards to human health and the environment and that is in the person's possession or to which the person ought reasonably to have access.

(2) A description or specification of the test procedures followed in developing the test data, including, for data developed on or after July 1, 1994 or for test procedures that are not prescribed, test methods, reference substances and quality control and quality assurance procedures.

(3) Notwithstanding subitem (2), in the case of a biotechnology product that is not derived from whole animals or whole plants, a description or specification of

SCHEDULE XII - *Concluded*

the test procedures followed in developing the test data, including, for data developed on or after September 1, 1997, or for test procedures that are not prescribed, test methods, reference substances and quality control and quality assurance procedures.

4. (1) A description of the plan for product development including the following information in respect of the polymer:

(a) the manufacturing and import activities;

(b) its storage;

(c) its transport;

(d) its intended uses;

(e) an assessment of the potential for its release into the environment or for persons to be exposed to it, and any measures that will be taken to protect against such release or exposure;

(f) the environmental fate; and

(g) analytical test methods that detect the polymer in the workplace and in the environment and that are in the person's possession or to which the person ought reasonably to have access.

(2) A complete description of the plan for disposing of the polymer outlining:

(a) all products in which the polymer will be used;

(b) the plan for recalling, recapturing and disposing of the polymer; and

(c) the ultimate mass balance of the polymer based on the quantity produced and its disposition.

SCHEDULE XIII

(Paragraphs 23(2)(b), subsections 23(3) and (4), paragraph 23.1(1)(b), subsections 24(3), 25(2) and 27(1) and (3), paragraph 27.1(1)(b) and section 28.1)

INFORMATION REQUIRED IN RESPECT OF POLYMERS THAT ARE SITE-LIMITED INTERMEDIATE SUBSTANCES OR MANUFACTURED OR IMPORTED FOR EXPORT ONLY

1. (1) The chemical name of the polymer, established in accordance with the chemical nomenclature rules of the International Union of Pure and Applied Chemistry or the Chemical Abstracts Service.

(2) The trade names of the polymer and the synonyms of its chemical name, if known.

(3) The Chemical Abstracts Service registry number of the polymer, if such a number can be assigned.

(4) The molecular formula of the polymer, if possible.

(5) The structural formula of the polymer, if possible, or else a partial structural formula of the polymer.

(6) The composition of the polymer, including constituents such as monomers, other reactants, known impurities expressed in per cent by weight and additives that are essential for the purpose of marketing.

(7) A material safety data sheet, as defined in subsection 11(1) of the *Hazardous Products Act*, in respect of the polymer, if available.

2. The following physical and chemical data in respect of the polymer:

(a) its number average molecular weight;

(b) the maximum concentrations, in per cent, of all residual constituents with molecular weights of less than 500 daltons and all residual constituents with molecular weights of less than 1 000 daltons;

(c) its physical state;

(d) its solubility in water at pH 7

(i) expressed in milligrams per litre, where its solubility is 10 mg/L or greater, and

SCHEDULE XIII - *Continued*

(ii) expressed as "less than 10 mg/L", where its solubility is less than 10 mg/L;

(e) its solubility in n-octanol or its octanol-water partition coefficient expressed, for solubility in n-octanol,

(i) in milligrams per litre, where its solubility is 50 mg/L or greater, and

(ii) as "less than 50 mg/L", where its solubility is less than 50 mg/L; and

(f) its solubility in water at pH 1 and pH 10, where its solubility is 50 mg/L or greater.

3. (1) Data from at least one acute mammalian oral toxicity test of the polymer.

(2) For the test referred to in sub-item (1), the following information:

(a) the age, sex, number, species, strain and source of the animals tested;

(b) the route by which the polymer is administered and the conditions under which the test is conducted; and

(c) the dose of the polymer, the vehicle by means of which the polymer is administered and the concentration of the polymer in the vehicle.

4. (1) All other information and test data in respect of the polymer that are relevant to identifying hazards to human health and the environment and that are in the person's possession or to which the person ought reasonably to have access.

(2) A description or specification of the test procedures followed in developing the test data, including, for data developed on or after July 1, 1994 or for test procedures that are not prescribed, test methods, reference substances and quality control and quality assurance procedures.

(3) Notwithstanding subitem (2), in the case of a biotechnology product that is not derived from whole animals or whole plants, a description or specification of the test procedures followed in developing the test data, including, for data developed on or after September 1, 1997, or for test procedures that are not prescribed, test methods, reference substances and quality control and quality assurance procedures.

5. A description of the manufacturing and import activities in respect of the polymer, information in respect of its storage, transport and intended uses, the potential for it to

SCHEDULE XIII - *Concluded*

be released into the environment or for persons to be exposed to it, any measures that will be taken to protect against such release or exposure and the environmental fate.

6. The identification of other government agencies, either abroad or within Canada, that the person has notified of the manufacture or importation of the polymer and the purpose of such notification.

SCHEDULE XIV

(Sections 10.1, 14.1, 23.1 and 27.1)

INFORMATION REQUIRED IN RESPECT OF BIOTECHNOLOGY PRODUCTS NOT DERIVED FROM WHOLE ANIMALS OR WHOLE PLANTS

1. The identification of the organism and the organ, if applicable, from which the biotechnology product is isolated, including

   (a) synonyms and common and superseded names, if known; and

   (b) the source and history.

2. A description of any known adverse human health or environmental effects associated with exposure to the production organism.

3. The concentration of the viable production organism in the final product.

4. A description of the method used to separate the production organism from the biotechnology product.

5. The identification of the encoded products, if known.

6. A description of any known biological activity or adverse human health or environmental effects associated with the nucleic acid or with the encoded products specified pursuant to item 5.

7. A description of all known catalytic functions.

8. The International Union of Biochemistry registry number, if available.

9. The known substrate specificity for each of the catalytic functions specified pursuant to item 7.

10. The optimum pH and temperature for the most appropriate substrates specified pursuant to item 9.

11. The catalytic constants K_m and K_{cat} and the conditions under which they are measured.

12. The known cofactors necessary for enzymatic activity.

13. The activity per unit weight of the final product.

Appendix 2 - Environment Canada Regional Offices

General information on the New Substances Notification Regulations and the Domestic Substances List as well as copies of both the NSN Forms are available from the Regional Offices of Environment Canada.

For residents of Newfoundland and Labrador, Prince Edward Island, Nova Scotia, and New Brunswick:

Environmental Protection Branch
Environment Canada
45 Aldemey Drive
Dartmouth, Nova Scotia
B2Y 2N6

Telephone: (902)426-9674
FAX: (902)426-3897

For residents of Quebec:

Environmental Protection Branch - Québec
Environment Canada
105 McGill Avenue, 4th Floor
Montréal, Québec
H2Y 2E7

Telephone: (514)283-4670
FAX: (514)496-6982

For residents of Ontario:

Environmental Protection - Ontario
Environment Canada
4905 Dufferin Street
Downsview, Ontario
M3H 5T4

Telephone: (416)739-5892
FAX: (416)739-4405

For residents of Manitoba, Alberta, Saskatchewan, and the Northwest Territories:

Environmental Protection - Prairie and Northern
Environment Canada
4999-98th Avenue, #200
Edmonton, Alberta
T6B 2X3

Telephone: (780)951-8766
FAX: (780)495-2758

For residents of British Columbia and the Yukon:

Environmental Protection - Pacific Yukon
Environment Canada
224 West Esplanade
North Vancouver, British Columbia
V7M 3H7

Telephone: (604) 666-2732
FAX: (604)666-6800

Appendix 3 - Naming Substances

1. Representing Substances with Well-defined Structures

1.1 Specific Substance Name

A name must be provided that unambiguously describes the substance using CAS or IUPAC nomenclature. Ambiguous or incomplete names are not appropriate for substance identification or for any subsequent publication on the DSL. Abbreviations, acronyms, laboratory designations, trade names, trademarks, or any trivial names that are not chemically descriptive should not be submitted. Further clarification of the level of specificity required is provided in Table 7.

Do not assume that an ambiguous name is adequate simply because there is only one isomer used in a particular industry or because the structural diagram has been provided with the notification.

Commercial dye names should not be used unless they are cross-referred to Colour Index Names in Volume 5 of the *Colour Index*. The *Colour Index* is a reference publication for manufacturers and users of dyes. It is published by the Society of Dyers and Colourists with assistance from the American Association of Textile Chemists and Colourists.

Inorganic substance names should identify all the elements and specify the element ratios. The use of empirical formulae or Stock Numbers is encouraged. (Stock Numbers are Roman numerals added parenthetically to indicate the state or states of oxidation).

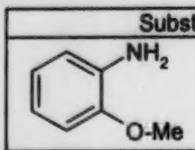
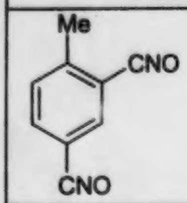
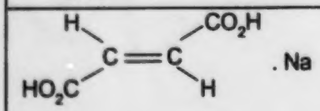
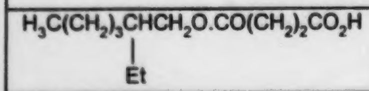
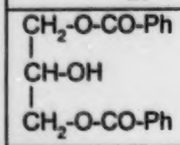
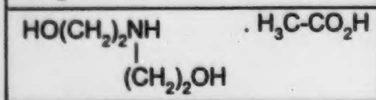
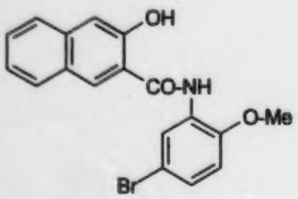
1.2 Molecular Formula

The molecular formula is a summation of the actual numbers and kinds of atoms present in a molecule of a substance. In the case of salts or addition compounds, the molecular formula may be presented as a single summation formula or in the "dot-disconnect" format used by CAS.

Example: Succinic acid, dilithium salt

$LiO_2C(CH_2)_2CO_2Li$		$HO_2C(CH_2)_2CO_2H \cdot 2Li$
$C_4H_4Li_2O_4$	or	$C_4H_6O_4 \cdot 2Li$
(summation)		(dot-disconnect)

Table 7 Specific Substance Names for Well-defined Substances

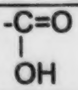
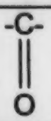
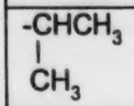
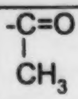
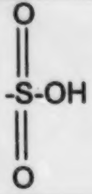
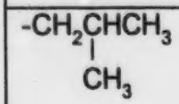
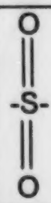
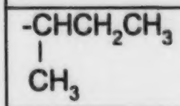
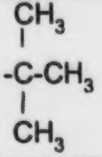
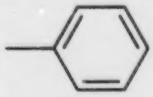
Substance	Unacceptable Name	Acceptable Name
	Anisidine	*o*-Anisidine or 2-Methoxyaniline
	Toluene diisocyanate or TDI	Toluene 2,4-diisocyanate
	Sodium fumarate or Monosodium butenedioate	Monosodium fumarate or Monosodium *trans*-butenedioate or Monosodium *E*-butenedioate
 $H_3C(CH_2)_3\underset{Et}{CH}CH_2O.CO(CH_2)_2CO_2H$	Octyl succinate or Ethylhexyl succinate	Mono(2-ethylhexyl) succinate
 $\begin{array}{l}CH_2\text{-}O\text{-}CO\text{-}Ph\\ \vert\\ CH\text{-}OH\\ \vert\\ CH_2\text{-}O\text{-}CO\text{-}Ph\end{array}$	Glycerol benzoate or Glycerol dibenzoate	Glycerol 1,3-dibenzoate
 $HO(CH_2)_2\underset{(CH_2)_2OH}{NH}\ .\ H_3C\text{-}CO_2H$	Diethanolamine acetate	Diethanolamine acetate salt
Ac-O-$(CH_2)_2NH(CH_2)_2$-O-Ac	Diethanolamine acetate or Diethanolamine acetate ester	Diethanolamine diacetate ester
Ac-O-$(CH_2)_2NH(CH_2)_2OH$	Diethanolamine acetate or Diethanolamine acetate ester	Diethanolamine monoacetate ester
	Blue APM or EMS 17	Brenthol BA or C.I. 37532 or C.I. Azoic Coupling Component 6 or 5'-Bromo-3-hydroxy-2-naphth-*o*-anisidine or *N*-(5-bromo-2-methoxyphenyl)-3-hydroxy-2-naphthalenecarboxamide
O=Ti-O-Ti=O	Titanium oxide	Titanium oxide (Ti_2O_3)

1.3 Structural Information

The structural diagram should clearly indicate the identity of the atoms and the nature of the bonds joining them. Guidelines for preparing these diagrams are included in this appendix.

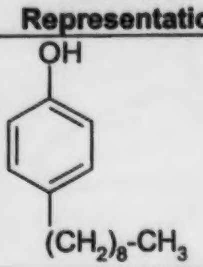
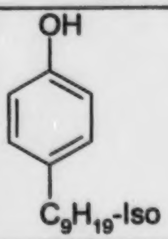
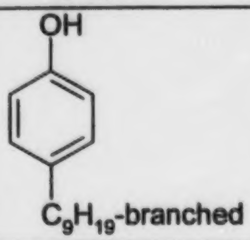
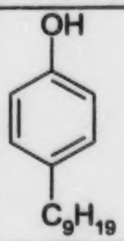
Common abbreviations are acceptable as long as they are unambiguous. Table 8 presents examples of abbreviations that may be used.

Table 8 Common Abbreviations that can be used to Indicate Structural Information

Structure	Abbreviation	Structure	Abbreviation
$-CH_3$	Me-	 $-\underset{\text{OH}}{\underset{\mid}{C}}{=}O$	$-CO_2H$
$-CH_2CH_3$	Et-	 $-\underset{O}{\underset{\Vert}{C}}-$	-CO-
$-(CH_2)_2CH_3$	Pr-	$-CH{=}O$	-CHO
 $-\underset{CH_3}{\underset{\mid}{C}}HCH_3$	-Pr-*i* or -Pr-*iso*	 $-\underset{CH_3}{\underset{\mid}{C}}{=}O$	-Ac
$-(CH_2)_3CH_3$	-Bu	 $-\overset{O}{\overset{\Vert}{\underset{O}{\underset{\Vert}{S}}}}-OH$	$-SO_3H$
 $-CH_2\underset{CH_3}{\underset{\mid}{C}}HCH_3$	-Bu-*i* or -Bu-*iso*	 $-\overset{O}{\overset{\Vert}{\underset{O}{\underset{\Vert}{S}}}}-$	$-SO_2-$
 $-\underset{CH_3}{\underset{\mid}{C}}HCH_2CH_3$	-Bu-*s* or -Bu-*sec*	$-N{=}O$	-NO
 $-\overset{CH_3}{\overset{\mid}{\underset{CH_3}{\underset{\mid}{C}}}}-CH_3$	-Bu-*t* or -Bu-*tert*		-Ph

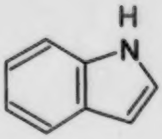
Alkyl groups will be assumed to be normal (linear) unless otherwise designated. If a substance has alkyl groups that are not linear, then the nature of the branching should be described as specifically as possible. Table 9 illustrates several different representations for nonylphenol.

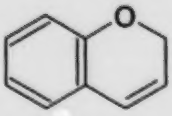
Table 9 Representations for Nonylphenol

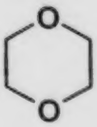
Submitted Name	Structural Representation	CAS Registry Number	CA Index Name
p-Nonylphenol		104-40-5	Phenol, 4-nonyl-
p-Isononylphenol		26543-97-5	Phenol, 4-isononyl-
Branched, 4-nonylphenol		84852-15-3*	Phenol, 4-nonyl-, branched
p-Tripropylene phenol		87247-00-5	Phenol, 4-tripropylene-

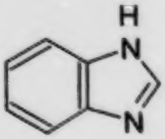
Carbon atoms in ring systems and their attached hydrogen atoms need not be explicitly shown.

For example:

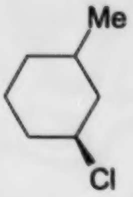




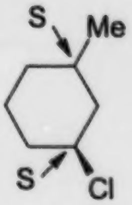




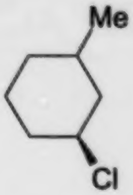
All known stereochemical details should be provided. Indicate whether the stereochemistry is absolute or relative. For example:



trans (relative)



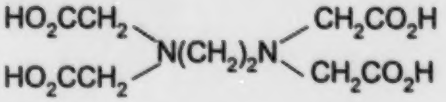
absolute

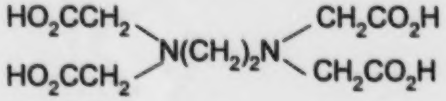


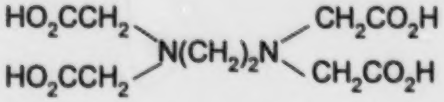
± (racemic)

The ratio of the components of an addition compound or salt should be clearly indicated if more than one form is theoretically possible. It should also be noted if the ratio is unknown.

For example:


$(HO_2CCH_2)_2N(CH_2)_2N(CH_2CO_2H)_2$. 2 Na


$(HO_2CCH_2)_2N(CH_2)_2N(CH_2CO_2H)_2$. 4 Na


$(HO_2CCH_2)_2N(CH_2)_2N(CH_2CO_2H)_2$. x Na

1.3.1 Examples of Well-defined Substances

The examples that follow illustrate the information necessary to uniquely identify and represent substances with a well-defined structure.

Example 1

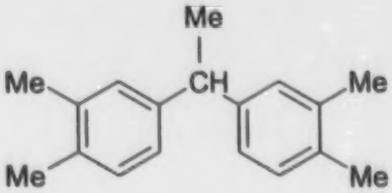
Specific Substance Name: N-(s-Butoxymethyl)acrylamide
Molecular Formula: $C_8H_{15}NO_2$
Structural Information: $H_2C{=}CH\text{-}CO\text{-}NH\text{-}CH_2\text{-}O\text{-}Bu\text{-}sec$ ***COMMENT:*** *Branching of alkyl groups must be indicated or the group will be assumed to be linear. For example, the Bu group on the following diagram would be represented linearly as -* $CH_2CH_2CH_2CH_3$ $H_2C{=}CH\text{-}CO\text{-}NH\text{-}CH_2\text{-}O\text{-}Bu$

Example 2

Specific Substance Name: 1,1-Di-3,4-xylylethane;
1,1-Bis(3,4-dimethylphenyl)ethane

Molecular Formula:
$C_{18}H_{22}$

Structural Information:



***COMMENT:** The semicolon is used to separate the two names. Both names cite locants. Dixylylethane would not be an appropriate name for this substance.*

Example 3

Specific Substance Name: Sodium sebacate;
Sodium decanedioate

Molecular Formula:
$C_{10}H_{18}O_4 . x Na$

Structural Information:

$HO_2C\text{-}(CH_2)_8\text{-}CO_2H\ .\ x\ Na$

***COMMENT:** Use of "x" in the molecular formula and structure diagram clearly indicates the ratio of the salt is unknown.*

Example 4

Specific Substance Name: Disodium sebacate;
Disodium decanedioate

Molecular Formula:
$C_{10}H_{18}O_4 . 2 Na$

Structural Information:

$$HO_2C\text{-}(CH_2)_8\text{-}CO_2H\ .\ 2\ Na$$

COMMENT: *When known, ratios should be cited in the name, formula, and structure. The formula could also be given as $C_{10}H_{16}Na_2O_4$. The structure could also be shown as:*

$$NaO_2C\text{-}(CH_2)_8\text{-}CO_2Na$$

Example 5

Specific Substance Name: 1,3-Pentadiene;
Piperylene

Molecular Formula:
C_5H_8

Structural Information:

$$H_2C{=}CH\text{-}CH{=}CH\text{-}CH_3$$

COMMENT: *Stereochemistry is not cited in the name or structure. See EXAMPLE 6 for a specific stereoisomer.*

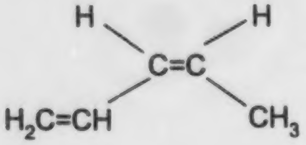
Example 6

Specific Substance Name: cis-1,3-Pentadiene; Z-1,3-Pentadiene; cis-Piperylene

---

Molecular Formula:
C_5H_8

Structural Information:



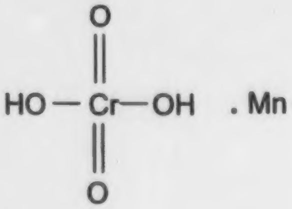
COMMENT: *Stereochemistry is cited in both the name and structure. See EXAMPLE 5 for an example of a non-stereospecific substance.*

Example 7

Specific Substance Name: Manganese (II) chromate (IV); Manganese chromate ($MnCrO_4$); Chromium manganese oxide ($MnCrO_4$)

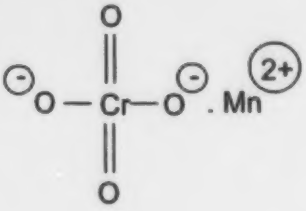
Molecular Formula:
H_2CrO_4Mn

Structural Information:



$$\mathrm{HO-\overset{\overset{\displaystyle O}{\|}}{\underset{\underset{\displaystyle O}{\|}}{Cr}}-OH \quad .\,Mn}$$

COMMENT: *Stock numbers or empirical formulae should be included in the name when known. The following diagram is also acceptable:*



$$\mathrm{{}^{\ominus}O-\overset{\overset{\displaystyle O}{\|}}{\underset{\underset{\displaystyle O}{\|}}{Cr}}-O^{\ominus}\ .\,Mn^{\textcircled{\scriptsize 2+}}}$$

Example 8

Specific Substance Name: PVC; Polyvinyl chloride

Molecular Formula:
$(C_2H_3Cl)_x$

Structural Information:

$ClCH{=}CH_2 + ABIN \rightarrow$ Polyvinyl chloride

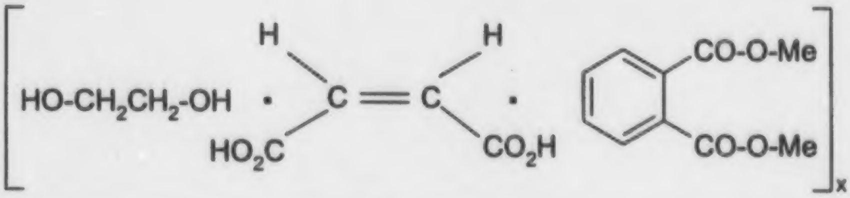
***COMMENT:** Polymeric substances are to be described in terms of their starting reactants. Starting reactants are defined as those that become part of the polymer composition. If the role of the reactant ABIN is an initiator, it should not be included in the polymer description appearing on the DSL. ABIN, if placed in commerce, must be reported separately.*

Example 9

Specific Substance Name: Maleic acid-dimethyl phthalate-ethylene glycol copolymer;
cis-2-Butenedioic acid-dimethyl phthalate-ethylene glycol polymer

Molecular Formula:
$(C_2H_6O_2\text{-}C_4H_4O_4\text{-}C_{10}H_{10}O_4)_x$

Structural Information:



Example 10

Specific Substance Name: Styrene-polyethyleneglycol monoallylether

Molecular Formula:
$((C_2H_4O)_n C_3H_6O.C_8H_8)_x$

Structural Information:

$$\left[\begin{array}{ll} H_2C{=}CH{-}CH_2{-}(O{-}CH_2{-}CH_2)_n{-}OH \;\cdot & Ph{-}CH{=}CH_2 \\ \text{CAS Registry Number} & \text{CAS Registry Number} \\ \text{27274-31-3} & \text{100-42-5} \end{array} \right]_x$$

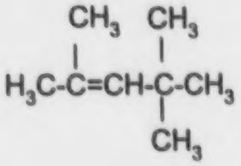
***COMMENT:** Names and CAS Registry Numbers rather than structure diagrams may be used to describe reactants. Polyglycol derivatives should be represented on the basis of their polymeric structure.*

Example 11

Specific Substance Name: 2,4,4-Trimethyl-2-pentene

Molecular Formula:
C_8H_{16}

Structural Information:



$$H_3C{-}\overset{\overset{CH_3}{|}}{C}{=}CH{-}\underset{\underset{CH_3}{|}}{\overset{\overset{CH_3}{|}}{C}}{-}CH_3$$

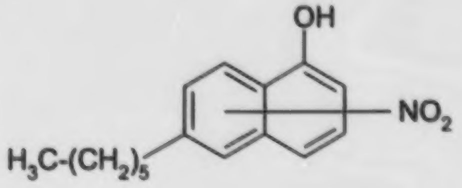
***COMMENT:** Isobutylene dimer would not be an appropriate specific substance name for this structure. Designations such as dimer and trimer are appropriate only when the degree of polymerization is a specific value from two through ten but the specific structure is unknown.*

Example 12

Specific Substance Name: ar-Nitro-6-hexyl-1-naphthol; ar-Nitro-6-hexyl-1-hydroxynaphthalene

Molecular Formula:
$C_{16}H_{19}NO_3$

Structural Information:



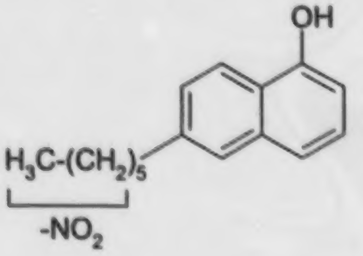
COMMENT: *Compare to EXAMPLES 13 and 14. The structural representation should represent all known specificity.*

Example 13

Specific Substance Name: 6-(Nitrohexyl)-1-naphthol;
6-(Nitrohexyl)-1-hydroxynaphthalene

Molecular Formula:
$C_{16}H_{19}NO_3$

Structural Information:



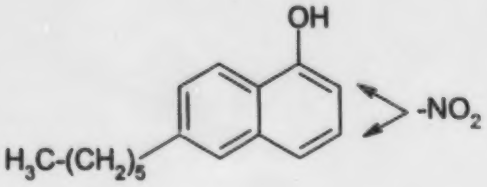
COMMENT: *Compare to EXAMPLES 12 and 14. The structural representation should represent all known specificity.*

Example 14

Specific Substance Name: 2 or 3-Nitro-6-hexyl-1-naphthol; 2 or 3-Nitro-6-hexyl-1-hydroxynaphthalene

Molecular Formula:
$C_{16}H_{19}NO_3$

Structural Information:



COMMENT: *Compare to EXAMPLES 12 and 13. The structural representation should represent all known specificity.*

Example 15

Specific Substance Name: Aluminum nickel

Molecular Formula:
Ni_3Al

Structural Information:

Ni_3Al

COMMENT: *Known stoichiometry should be indicated. Ni-Al would be unacceptable.*

Example 16

Specific Substance Name: Synthetic geikielite

Molecular Formula:
$Mg\text{-}O_3Ti$

Structural Information:

COMMENT: *Synthetic minerals should indicate in the Specific Substance Name that they are synthetic.*

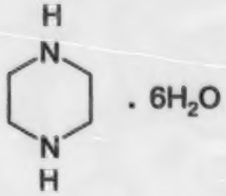
Example 17

Specific Substance Name:	Piperazine hexahydrate; Arpezine

Molecular Formula:

$C_4H_{10}N_2 \cdot 6H_2O$

Structural Information:



***COMMENT:** Substances that are described as hydrates should be represented as the anhydrous form.*

2. *Representing Substances that are Complex and Variable*

Substances that cannot be represented by a complete structure diagram and specific molecular formula are known as substances of Unknown or Variable Composition, Complex reaction products, or Biological materials (UVCBs).

2.1 *Specific Substance Name*

The guidelines for names for UVCB substances are similar to the instructions given in Subsection 1.3.1 of Appendix 3 for Well-Defined Substances and should be reviewed for additional information. See Table 10 for further clarification of the level of specificity required.

Table 10 Specific Substance Names for Complex and Variable Substances

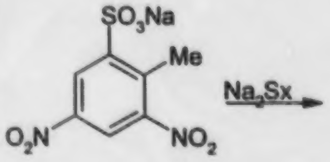
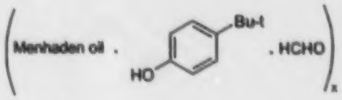
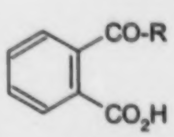
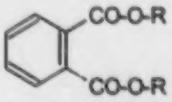
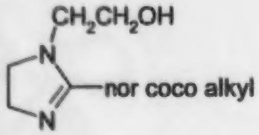
Substance	Unacceptable Name	Acceptable Name
	RGP Brown or Sodium dinitrotoluenesulfonic acid polysulfide	C.I. Sulphur Brown 42 or C.I. 53030 or Thionone Brown R0 or Sodium 3,5-dinitro-o-toluenesulfonic acid reaction product with sodium polysulfide
$H_2C{=}CH{-}R$ $\xrightarrow[\text{chlorination}]{\text{bromination}}$ R = $C_{10\text{-}28}$ Alkyl	Halogenated $C_{12\text{-}30}$ α-alkenes or Bromo and chloroalkenes	$C_{12\text{-}30}$ α-alkenes bromo and chloro derivs. or $C_{12\text{-}30}$ α-(alkenes, brominated and chlorinated) or Alkenes, $C_{12\text{-}30}$ α-brominated and chlorinated
	Fish oil-butyl phenol-formaldehyde resin or Marine oil, *p-tert*-butylphenol, formaldehyde resin or Menhaden oil, 4-butylphenol, formaldehyde resin	Menhaden oil, *p-tert*-butylphenol, formaldehyde resin
Linseed oil fatty acids . xNa	Vegetable fatty acids sodium salts or Linseed sodium salts or Linseed oil sodium salts	Linseed oil fatty acids sodium salts or Fatty acids, linseed-oil, sodium salts
 R = $C_{8\text{-}10}$ branched alkyl	Nonyl phthalate or Isononyl phthalate or Mono-$C_{8\text{-}10}$-alkyl phthalate	Mono-$C_{8\text{-}10}$-branched alkyl phthalate or 1,2-Benzenedicarboxylic acid, mono-$C_{8\text{-}10}$-branched alkyl esters
 R = $C_{8\text{-}10}$ branched alkyl	Dinonyl phthalate or Diisononyl phthalate or Di-$C_{8\text{-}10}$-alkyl phthalate	Di-$C_{8\text{-}10}$-branched alkyl phthalate or 1,2-Benzenedicarboxylic acid, di-$C_{8\text{-}10}$-branched alkyl esters

Table 10 Specific Substance Names for Complex and Variable Substances (*continued*)

Substance	Unacceptable Name	Acceptable Name
Coconut oil fatty acids $+ \xrightarrow[\text{formation}]{\text{salt}}$ $HOCH\ CH_2NHCH_2CH_2OH$	Coconut oil fatty acids reaction product with diethanolamine	Coconut oil fatty acids-diethanolamine salt or Coconut oil fatty acids, compound with diethanolamine or Fatty acids, coco, compds. with diethanolamine
$HOCH_2CH_2NHCH_2CH_2O\text{-}CO\text{-}R$ -CO-R = coco fatty acyl	Coconut oil fatty acids reaction product with diethanolamine	Coconut oil fatty acids diethanolamine monoester or Fatty acids, coco, 2-[[(2-hydroxyethyl)amino]ethyl] esters
	Coconut oil reaction product with aminoethyl ethanolamine or Coco alkylimidazolineethanol	Coconut oil and *N*-(2-aminoethyl)ethanolamine cyclization product or 1*H*-Imidazole-ethanol, 4,5-dihydro-2-norcoco alkyl derivs.

2.2 *Molecular Formula*

Most UVCB substances cannot be represented by a specific molecular formula. However, in some cases, it may be possible to provide a molecular formula that is a summation of the range of numbers and specific kinds of atoms present in a molecule of a substance. Hypothetical or idealized molecular formulae must not be cited.

Molecular formulae for salts and addition compounds, if provided, may be presented as a single summation formula or in the dot-disconnect format used by CAS.

Example: $C_{6\text{-}12}$-alkyldicarboxylic acid, disodium salt

$NaO_2C\text{-}C_{6\text{-}12}\text{alkyl-}CO_2Na$ $HO_2C\text{-}C_{6\text{-}12}\text{alkyl-}CO_2H \cdot 2Na$

$C_{8\text{-}14}H_{12\text{-}24}Na_2O_4$ or $C_{8\text{-}14}H_{14\text{-}26}O_4 \cdot 2Na$

2.3 *General Guidelines*

Because, in most cases, a unique structure diagram cannot be provided, descriptive information for the substance, components, or precursors should be given.

If a partial structural diagram can be provided, this diagram should clearly indicate the identity of the atoms and the nature of the bonds joining them. Common abbreviations for substituents and functional groups are acceptable if they are unambiguous. Alkyl groups will be assumed to be normal (linear) unless otherwise designated.

Substance representations should describe all known specificity, such as salt ratios and stereochemical details.

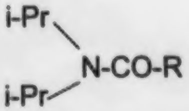
The examples are intended to illustrate the level of specificity that should be provided. It is strongly recommended that the notifier follow the style of the examples.

Example 18

Specific Substance Name: *N*,*N*-Diisopropyl tall oil fatty amides

Molecular Formula:

Structural Information:



-CO-R = tall oil fatty acyl

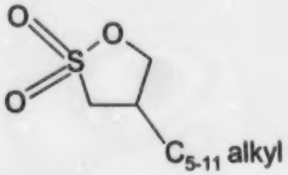
COMMENT: *A substance can be described in terms of a partial structure diagram.*

Example 19

Specific Substance Name: 4-(C_{5-11}-alkyl)-1,2-oxathiolane, *S*,*S*-dioxide

Molecular Formula:

Structural Information:



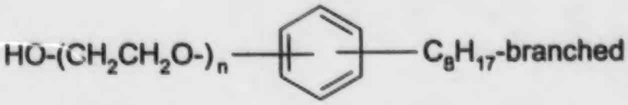
COMMENT: *Carbon ranges of alkyl groups must be defined.*

Example 20

Specific Substance Name: C_8 branched alkylphenol ethoxylate

Molecular Formula:

Structural Information:


HO-(CH₂CH₂O-)ₙ
C₈H₁₇-branched

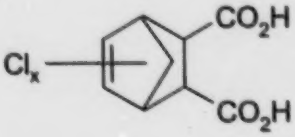
***COMMENT:** Representations should describe all known specificity, including structural information for alkyl groups.*

Example 21

Specific Substance Name: Chlorinated 5-norbornene-2,3-dicarboxylic acid; Bicyclo[2.2.1]hept-5-ene-2,3-dicarboxylic acid, chloro derivs.

Molecular Formula:

Structural Information:

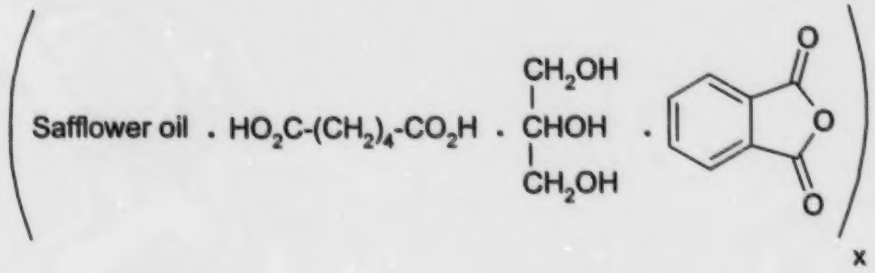

Cl_x
CO_2H
CO_2H

Example 22

Specific Substance Name: Safflower oil, polymer with adipic acid, glycerol and phthalic anhydride

Molecular Formula:

Structural Information:


Safflower oil
.
$HO_2C-(CH_2)_4-CO_2H$
.
CH_2OH
CHOH
CH_2OH
.
O
O
O
x

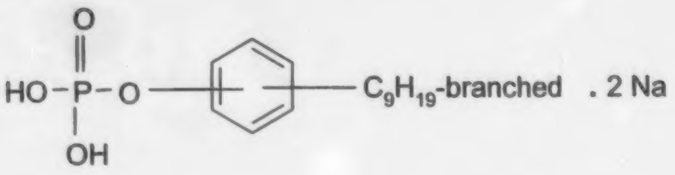
Example 23

Specific Substance Name: Phosphoric acid, mono(branched nonyl) phenyl ester, disodium salt

Molecular Formula:

$C_{15}H_{25}O_4P \cdot 2\ Na$

Structural Information:



2.4 *Plant and Animal Products*

Complex and variable substances, which are produced by chemical modification of naturally occurring products or are separated from them by physical processing[8], must be identified by specifying the genus and species as well as other unambiguous common names of the source.

Do not assume that a common name is adequate simply because there is only one source used in a particular industry. For example, mint oil should not be used to identify Japanese mint oil, Bergamot oil, Spearmint oil, or Peppermint oil. Vegetable oil should not be used to identify corn oil, soybean oil, or linseed oil.

The examples are intended to illustrate the level of specificity that should be provided.

Example 24

Specific Substance Name: Soybean fatty acids, diethylenetriamine salt

Molecular Formula:

Structural Information:

Soya fatty acids . x $H_2NCH_2CH_2NHCH_2CH_2NH_2$

---

[8] Physical processing includes such methods as: distillation; steam distillation; crystallization; sublimation; salting out; ion-exchange; and heating for reasons other than to remove water.

Example 25

Specific Substance Name: Mixed vegetable oils fatty acids methyl esters

Molecular Formula:

Structural Information:

Methyl esters of mixed vegetable oils fatty acids

COMMENT: *If a substance is obtained from a manufacturing process that used different types of plants to produce an oil, then the term, "mixed vegetable" should be used in the name.*

Example 26

Specific Substance Name: Japanese mint oil;
Japanese peppermint oil

Molecular Formula:

Structural Information:

Oil extracted from *Mentha arvensis* var. *piperascens*

COMMENT: *The genus and species of the plant that was processed to produce the oil must be identified.*

Example 27

Specific Substance Name: *Mentha citrata* oil;
Bergamot mint oil

Molecular Formula:

Structural Information:

Oil extracted from *Mentha citrata*

COMMENT: *Bergamot oil would not be an appropriate specific substance name because bergamot oil is also extracted from* Citrus bergamia.

Example 28

Specific Substance Name: Acetylated lemongrass oils

Molecular Formula:

Structural Information:

Lemongrass oil $\xrightarrow{\text{acetylation}}$
8007-02-1*

***COMMENT:** The genus and species,* Cymbopogon citratus, *is associated with CAS Registry Number 8007-02-1* in the Chemical Definition Section of TSCA.*

Example 29

Specific Substance Name: Terpene-free bergamot oil fraction

Molecular Formula:

Structural Information:

Terpene-free fraction distilled from oil extracted from *Citrus bergamia*.

Example 30

Specific Substance Name: Corn oil deodorizer distillate

Molecular Formula:

Structural Information:

A complex mixture of fatty acids, sterols, aldehydes, ketones, and other materials prepared by the steam distillation of corn oil followed by condensation of the steam containing these materials.

2.5 Reaction Products

The reaction scheme should include the chemical identity of the immediate precursors, the nature of the reaction, and the reactants, whether or not they are implied by the reaction term. Reaction terms should be as specific as possible (e.g., acetylation, alkaline hydrolysis, chlorination, diazotization, epoxidation). General reaction terms such as addition, condensation, and reaction should not be used.

Although the substance itself may be a UVCB substance, the precursors or components may be well-defined substances. Any descriptions provided for well-defined precursors or components should meet the specifications discussed previously.

The examples are intended to illustrate the level of specificity that should be provided.

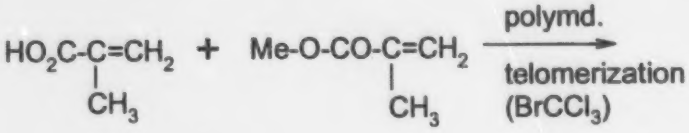
Example 31

Specific Substance Name: Polymer of methyl methacrylate, methacrylic acid, and bromotrichloromethane

Molecular Formula:

$(C_4H_6O_2 . C_5H_8O_2)_x \cdot xCBrCl_3$

Structural Information:



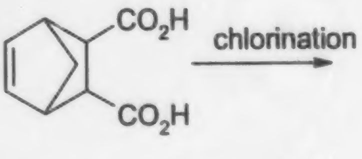
$$HO_2C\text{-}\underset{\underset{CH_3}{|}}{C}{=}CH_2 + Me\text{-}O\text{-}CO\text{-}\underset{\underset{CH_3}{|}}{C}{=}CH_2 \xrightarrow[\text{telomerization}\ (BrCCl_3)]{\text{polymd.}}$$

Example 32

Specific Substance Name: Chlorinated 5-norbornene-2,3-dicarboxylic acid; Bicyclo[2.2.1]hept-5-ene-2,3-dicarboxylic acid, chloro derivs.

Molecular Formula:

Structural Information:



COMMENT: *Compare to EXAMPLE 21. Either method is acceptable. Both depict the same degree of specificity.*

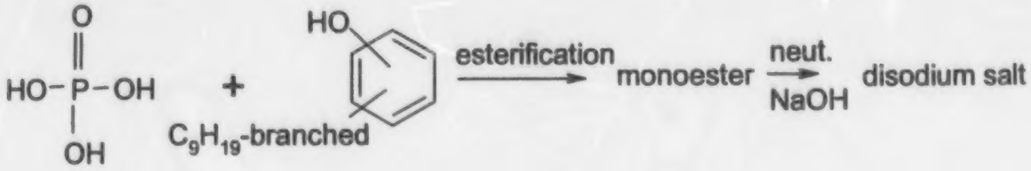
Example 33

Specific Substance Name: Phosphoric acid, mono(branched nonyl) phenyl ester, disodium salt

---

Molecular Formula:

Structural Information:


HO
C_9H_{19}-branched
esterification
monoester
neut.
NaOH
disodium salt

***COMMENT:** Compare to EXAMPLE 23. Either method is acceptable. Both depict the same degree of specificity.*

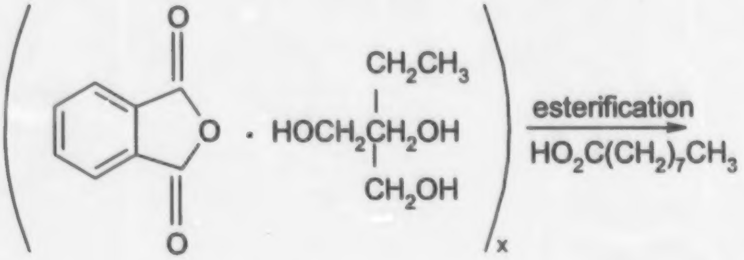
Example 34

Specific Substance Name: Phthalic anhydride-trimethylolpropane copolymer, pelargonate

---

Molecular Formula:

Structural Information:

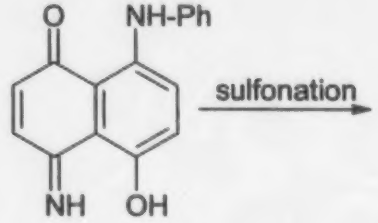

$HOCH_2CH_2OH$
CH_2CH_3
CH_2OH
x
esterification
$HO_2C(CH_2)_7CH_3$

Example 35

Specific Substance Name: C.I. Acid Black 47; C.I. 56055;
Sulfonine Grey G

Molecular Formula:

Structural Information:



Example 36

Specific Substance Name: Tallow fatty acid ethanolamine amides salt

---

Molecular Formula:

Structural Information:

Tallow fatty acids + $H_2NCH_2CH_2OH \rightarrow$ amides

COMMENT: *Because tallow fatty acids and ethanolamine may react to form a variety of different products (e.g., salts, esters, cyclization products), the product description should be as specific as possible and include typical composition.*

2.6 Products from Industrial Processes

Some Complex and Variable substances are most conveniently described by text rather than structural diagrams or reaction schemes.

The description should include precursors, method of preparation, process terms (low-boiling, catalytic reformed), physical properties (if known), and typical chemical composition. Specifically, the substance information should describe the substance as uniquely as possible and include (if known):

(a) process description (catalytic cracking, dewaxed, destructive distillation);

(b) carbon (alkyl) range (C_4 through C_{12});

(c) physical properties (boiling range, viscosity, solid, slag, and softening point);

(d) principal chemical composition (hydrocarbons, sulfides, terpenes);

(e) source (e.g., petroleum, coal)

It is recommended that, whenever appropriate, schematic diagrams (depicting the industrial process and the point where the notified substance is isolated) be provided.

The description should not include process terms that are unqualified or broadly descriptive or undefined trade jargon.

The examples are intended to illustrate the level of specificity that should be provided. Additional examples of the type of descriptive information required can be found in the Chemical Substance Definitions sections of TSCA.

Example 37

Specific Substance Name: $C_{9\text{-}13}$ Alkylbenzene distillation residues

Molecular Formula:

Structural Information:

Complex residue from the distillation of $C_{9\text{-}13}$ alkylbenzenes having a boiling point >600 °F. Composed primarily of diphenylalkanes, dialkylbenzenes, and diphenyldialkanes. The alkyl groups are linear $C_{9\text{-}13}$.

Example 38

Specific Substance Name: Ferrous metals blast furnace slag

Molecular Formula:

Structural Information:

Fused substance formed by the action of a flux on the gangue of iron-bearing materials charged to the blast furnace and on oxidized impurities in the iron produced. Composed primarily of sulfur and oxides of Al, Ca, Mg, and Si.

Example 39

Specific Substance Name: Oxidized black liquor;
Spent pulping liquor, oxidized

Molecular Formula:

Structural Information:

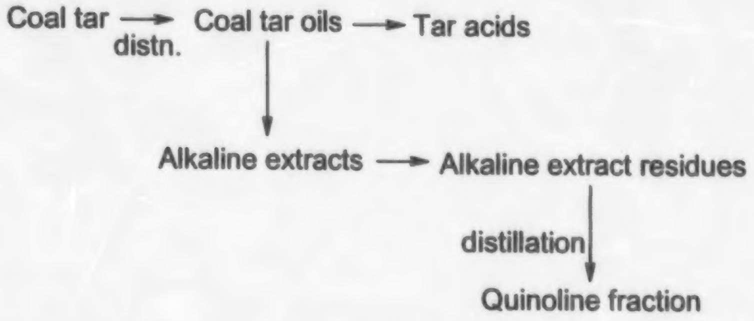
Substance produced by the oxidation of black liquor with pulping chemicals used in Kraft, sulfite, semichemical, or other pulping processes. Composed primarily of partially oxidized lignosulfonates, sugars, and hemicelluloses.

Example 40

Specific Substance Name: Quinoline fraction of coal tar alkaline extract residues

Molecular Formula:

Structural Information:


Coal tar
distn.
Coal tar oils
Tar acids
Alkaline extracts
Alkaline extract residues
distillation
Quinoline fraction

Quinoline fraction consists primarily of quinoline, isoquinoline, methylquinolines, and dimethylquinolines.

Example 41

Specific Substance Name: Coal coke

Molecular Formula:

Structural Information:

Carbonaceous residue from the high temperature (> 700 °C) destructive distillation of coal. Composed primarily of carbon but may contain sulfur and ash.

Example 42

Specific Substance Name: Petroleum coke

Molecular Formula:

Structural Information:

Carbonaceous residue from the high temperature destructive distillation of petroleum fractions. Composed primarily of carbon but may contain some hydrocarbons with high carbon to hydrogen ratios.

Example 43

Specific Substance Name: Naphtha, petroleum, hydrodesulfurized full-range

Molecular Formula:

Structural Information:

A complex combination of hydrocarbons obtained from a catalytic hydrodesulfurization process. It consists of hydrocarbons having carbon numbers predominantly in the range of C_4 through C_{12} and in the boiling range of approximately 30 to 250 °C.

Example 44

Specific Substance Name: Copper smelting slag

Molecular Formula:

Structural Information:

Substance resulting from the smelting of copper and precious metals obtained from primary and secondary sources and plant reverts. Composed primarily of iron oxides and SiO_2. May contain Cu, Pb, Ni, and other non-ferrous metals and oxides.

Example 45

Specific Substance Name: Olivine vanadium blue

Molecular Formula:

Structural Information:

An inorganic pigment formed by the high temperature calcination of vanadium (IV) oxide and silicon oxide in varying amounts. Ionic diffusion occurs to form a crystalline matrix. Alkali or alkaline earth halides may be included as modifiers.

2.7 *Combinations of UVCB Substances*

Because of their complexity, it is necessary to describe the precursors, reactants, reaction scheme, and nominated substance as specifically as possible when notifying substances produced by the combination of UVCB substances. It is strongly recommended that before reporting these types of substances all sections of this appendix be carefully reviewed.

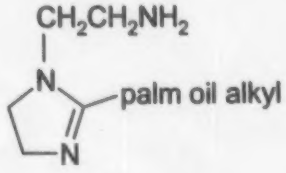
The examples are intended to illustrate the level of specificity that should be provided.

Example 46

Specific Substance Name: Palm oil and diethylenetriamine cyclization product, compound with distillation residue

Molecular Formula:

Structural Information:



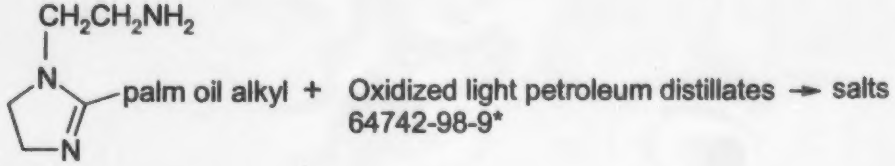
Residue from distillation of C_{6-18} saturated and unsaturated monobasic acids and C_{8-15} dibasic acids. Consists of — Salts C_{9-18} saturated dibasic acids. May also contain polymers, anhydrides, and polyesters.

Example 47

Specific Substance Name: Palm oil and diethylenetriamine cyclization product, compound with oxidized light petroleum distillates

Molecular Formula:

Structural Information:


$CH_2CH_2NH_2$
N
N
palm oil alkyl +
Oxidized light petroleum distillates → salts
64742-98-9*

***COMMENT:** The use of CAS Registry Number 64742-98-9* eliminates the need for the inclusion of a lengthy description of the starting material.*

Example 48

Specific Substance Name: Oxidized sesquiterpene fraction of Cedarwood oil
Molecular Formula:
Structural Information: Sesquiterpene fraction distilled from oil extracted from *Cedrus atlantica*, Pinaceae. $\xrightarrow{\text{oxidation}}$

Appendix 4 - Locating Chemical Abstracts Service Registry Numbers

To assist notifiers in their efforts to locate CAS Registry Numbers, sources that may be used to identify CAS Registry Numbers are described.

1. Toxic Substances Control Act (TSCA) Chemical Substance Inventory

The TSCA Inventory of 1985 published by the U.S. EPA is an inventory of over 58 000 chemical substances manufactured, imported, or processed in the United States of America. The inventory consists of five volumes that can be used to identify CAS Registry Numbers.

Volume I is the list, in ascending CAS Registry Number, of chemical substances submitted in compliance with TSCA. It can be used if the CAS Registry Number for a substance is known, and the submitter wishes to verify that it represents the substance that is being reported. This verification is done by reviewing the CA Index or Preferred Name associated with the CAS Registry Number. It should describe the substance in question precisely. A dagger (†) after the CAS Registry Number indicates that additional descriptive information necessary for unambiguous identification of the substance is provided in the Chemical Substance Definitions section found in Volume I; this information should be reviewed to ensure accurate verification.

Volumes II and III are the Substance Name section of TSCA and should be used if a substance name is available. This section is an alphabetical listing of chemical names including CA Index or Preferred Names, TSCA submitted chemical names, and CAS synonyms that are associated with the corresponding CAS Registry Number. Examine the adjacent entries or search for a permutation of the name when a particular name is not found. Numeric and alphabetic prefixes, Roman or Greek letters or numbers used as locants, and alternate spellings (e.g., sulfur and sulphur) and punctuation may affect the alphabetic sequence. The abbreviation C.I. is alphabetized as if were expanded to *Colour Index*.

It is not uncommon for a single nonsystematic name to be associated with two or more different substances. Trademarks, trade names, and names that do not specify locants or ratios are ambiguous. When such a name is located, look for the CAS Registry Number in Volume I, and review the specific CA Index or Preferred Name associated with that CAS Registry Number to ensure that the CAS Registry Number represents the substance that is to be notified.

Volume IV is the Molecular Formula section of TSCA and should be used if the molecular formula of a substance is known. This section lists TSCA substances of known chemical constitution according to the Hill System. Review the name(s) cited below the molecular formula to find the CAS Registry Number for the substance to be notified. Note that when using the Molecular Formula Index, names of chemical salts and molecular addition compounds will, in most cases, be found under the molecular formula of the acid. For example, the substance name trisodium salt of phosphoric acid would be found under the molecular formula of the substance name for phosphoric acid (H_3PO_4).

Volume V, which is the UVCB section, should be used if a molecular formula cannot be calculated and an appropriate entry for the substance has not been located in the Name section. This Index is an alphabetic list of Subset Headings with associated CAS Registry Numbers and CA Preferred Names for substances of Unknown or Variable Composition, Complex Reaction Products, and Biological Materials (UVCBs). Subset Headings identify categories of closely related UVCB substances and provide a method of organizing UVCBs into subsets containing a relatively small number of entries.

2. *European Inventory of Existing Commercial Chemical Substances (EINECS)*

EINECS (the Advance Edition) published by the Commission of the European Communities is an inventory of over 100 000 chemical substances that includes substances from the European Core Inventory (ECOIN) and that were declared to be on the European Community market between January 1, 1971 and September 18, 1981. This Advance Edition is divided into a Master Inventory and five supplementary Indexes (a Name Index, a Molecular Formula Index, a UVCB Index, a Definition Index, and a Plant Name Index). The Master Inventory is a list of the chemical substances in ascending order according to their EINECS Number and their CAS Registry Number. It also provides the chemical name, molecular formula, and substance definition, if appropriate. The Name Index, the Molecular Formula Index, and the UVCB Index are similar to the corresponding indexes that were described for the TSCA Inventory.

3. *Chemical Abstracts*

Chemical Abstracts contains abstracts and index entries selected from scientific and technical literature. The weekly issues and volume indexes provide access to the world literature for chemical substances. At present, CAS publishes two complete volumes of abstracts and their corresponding indexes for each calendar year. The indexes to each volume include a Formula Index, a Chemical Substance Index, and a General Subject Index. The Formula Index provides CA Index Names, CAS Registry Numbers, and abstract numbers for chemical substances identified by molecular formula. Entries are arranged according to the Hill System. The Chemical Substance Index links the CA Index Name, which identifies a specific chemical substance, with an abstract number. CA Index names are listed in alphabetical order and CAS Registry Numbers are given. The General Subject Index links subject terms, such as reactions, classes of substances, and plant and animal species, with their corresponding CA Abstract Numbers.

4. *Chemical Abstracts Index Guide*

To help users of CA Indexes locate substances and other information, CAS publishes the CA Index Guide. The CA Index Guide details the major points of CA indexing policy and provides cross-references, from various subject terms and substance names used in the literature, to the controlled CA indexing terminology and CAS Registry Numbers, if applicable. For substance identification, this publication provides many cross-references to common names and the CA Index Name and CAS Registry Number.

5. *Registry Handbook - Common Names*

A microform publication, this handbook is an alphabetical list of common names, CA Index Names, and other related names; associated with each name is the corresponding CAS Registry Number and molecular formula. There are over 1 250 000 names and 500 000 CAS Registry Numbers in this publication.

6. *Registry Handbook - Number Section*

This publication, in ascending CAS Registry Number order, provides CA Index Names and molecular formulas for over seven million substances. The "base book" covers 1965 to 1971. Additions are provided in annual supplements based on specific Registry Number ranges.

7. *Chemical Abstracts Service ONLINE*

The CAS ONLINE is a comprehensive chemical information database that offers substance-oriented and subject-oriented searching. This database makes information on chemical and related disciplines available through three related files - the Registry File for substance identification, the CA File for bibliographic searching, and the CAOLD File for reference to pre-1967 literature. CAS ONLINE is available on STN International by direct telephone link through most telecommunications networks. The Registry File contains information on over nine million substances reported in the literature, with over 10 000 new entries added every week. CAS Registry Numbers for chemical substances can be identified by searching this File using molecular formulas, substructures, or a variety of chemical dictionary terms such as chemical names or name fragments.

8. *Chemical Abstracts Service Registry Services*

Using CAS Registry Services, notifiers can obtain CAS Registry Numbers for their substances or CA Index Names for confidential substances. This service furnishes CAS Registry Numbers to customers either by retrieving existing CAS Registry Numbers and/or assigning new CAS Registry Numbers for chemical substances that meet CAS criteria for registration.

9. *The Cosmetic, Toiletry and Fragrance Association Cosmetic Ingredient Dictionary*

This book, published by The Cosmetic, Toiletry and Fragrance Association, Inc. (CFTA), provides nomenclature recommendations for ingredients of formulations used by the cosmetic industry. It is an alphabetical listing of CTFA Adopted Names with associated substance information; this information includes CAS Registry Numbers, CTFA Recognized Disclosure Numbers, definitions, structures, and related chemical or trade names. CAS Registry Numbers have been included in the monographs for many of the CTFA Adopted Names and are included in a numerical listing in Section VIII of this dictionary.

10. *International Nonproprietary Names for Pharmaceutical Substances*

This publication is a computer printout of several lists of international nonproprietary names (INN) that are published regularly in the EHO Chronicle. It includes the INN in Latin, English, French, Russian, and Spanish and references to the numbers of proposed and recommended lists in which they have been published; it also includes other data such as references to national nonproprietary names, pharmacopoeia monographs, molecular formulae, and CAS Registry Numbers.

11. *Registry of Toxic Effects of Chemical Substances (RTECS)*

This publication from the U.S. Department of Health and Human Services is a compendium of toxicity data extracted from the scientific literature and is prepared in compliance with the *Occupational Safety and Health Act* of 1970. The RTECS contains names of different chemicals with their associated toxicity data, synonyms, molecular formula, RTECS Number, and CAS Registry Number. There is a CAS Registry Number - RTECS Number Index that permits the reader to look up the RTECS data record of a substance when only its CAS Registry Number is known.

12. *The Merck Index*

The Merck Index published by Merck and Company Inc., is an alphabetical listing of chemicals, drugs, pesticides, and biologically active substances. The monograph for each listing contains substance data such as chemical names, drugs code numbers, literature references, toxicity data, CAS Registry Numbers, and generic names.

13. *USAN and the USP Dictionary of Drug Names*

This publication by the United States Pharmacopeial Convention, Inc. is a dictionary of nonproprietary names, brand names, code designations, and CAS Registry Numbers for drugs. The names are listed in alphabetical order by INN.

Appendix 5 - Examples of Waiver Conditions

The requirement to provide test data on a chemical or polymer may be waived if sufficient justification is given. Examples of conditions under which waivers may be granted will be described. These and other conditions for granting a waiver of information will be considered on a case-by-case basis.

1. Physical and Chemical Data

1.1 Density

(a) The substance is only stable in solution in a particular solvent and the solution density is similar to that of the solvent. In such cases, an indication of whether the solution density is higher or lower than the solvent density would be sufficient.

1.2 Vapour Pressure

(a) The substance has a vapour pressure less than 10^{-5} Torr (1.3×10^{-3} Pa), in which case an approximate value should be given.

1.3 Water Solubility

(a) The substance reacts dangerously with water (e.g., liberates a poisonous gas).

(b) The substance is highly volatile; therefore, determination of water solubility is not technically feasible.

(c) The substance has a water solubility less than 10^{-6} g/L, in which case an approximate value should be given.

1.4 Partition Coefficient

(a) The substance decomposes or reacts dangerously during the performance of the test.

(b) The substance is surface active.

1.5 Adsorption-Desorption

(a) The solubility of the substance in water cannot be measured analytically; therefore, determination of adsorption is not technically feasible.

(b) The substance has a very high water solubility (e.g., greater than 100 g/L) and its solubility in octanol or fat is less than one thousandth of its water solubility (e.g., log K_{ow} less than -3).

(c) The substance decomposes (e.g., biodegradation or hydrolysis) or reacts dangerously during the performance of the test.

1.6 Dissociation Constant(s)

(a) The solubility of the substance in water cannot be measured analytically; therefore, determination of dissociation constant(s) is not technically feasible.

(b) The substance reacts dangerously with water.

(c) The pK_a of the substance is less than 3 or greater than 10.

1.7 Hydrolysis as a Function of pH (Screening Portion)

(a) The substance reacts dangerously with water.

(b) The substance is a member of one or more of these groups and does not contain other functional groups that could change the hydrolysis potential of the substance:

Alcohols
Aldehydes
Alkanes
Alkenes
Alkynes
Aromatic amines
Aromatic nitro compounds

Benzenes/Biphenyls
Carboxylic acids
Ethers

Glycols
Halogenated aromatics
Heterocyclic polycyclic aromatic hydrocarbons
Ketones
Phenols
Polycyclic aromatic hydrocarbons

Sulphonic acids

1.8 Particle Size or Fibre Length

(a) The substance is unlikely to be in a powder form (e.g., an amorphous waxy solid).

(b) The substance does not contain particles having an aerodynamic diameter less than 10 μm.

1.9 Fat Solubility

(a) The substance decomposes or reacts during the performance of the test.

(b) The substance is highly volatile; therefore, determination of fat solubility is not technically feasible.

(c) The substance has a very high water solubility (e.g., greater than 100 g/L) and its octanol solubility is less than one thousandth of its water solubility (e.g., log K_{ow} less than -3)

1.10 Number-average Molecular Weight

(a) The polymer cannot be dissolved in any solvent suitable for use in an analytical method.

1.11 Concentration of Residual Constituents

(a) The polymer cannot be dissolved in any solvent suitable for use in an analytical method.

(b) A residual constituent of the substance cannot be measured analytically; therefore, determination of its concentration is not technically feasible.

1.12 Ultraviolet - Visible Spectrum

(a) The substance is explosive or reacts dangerously in the presence of light.

2. Toxicological Data

2.1 Acute Toxicity (Oral, Dermal, or Inhalation)

(a) The substance is corrosive or highly irritating, or is expected to be corrosive or highly irritating based on consideration of factors such as pH and chemical reactivity; therefore, administration of the substance in accordance with the test protocol for the acute toxicity test would cause severe and enduring pain to the test animals.

(b) It is not technically feasible to administer known doses of the substance because of its chemical or physical properties (e.g., the substance is a gas that cannot be dissolved to a detectable level into an appropriate oral vehicle).

2.2 Repeated Dose Toxicity (Oral, Dermal, or Inhalation)

(a) The substance is incorporated into a matrix and will not be released during its intended use, or any reasonable misuse. The matrix must be able to resist physical, chemical, and biological degradation.

(b) It is not technically feasible to administer known doses of the substance because of its chemical or physical properties.

(c) The substance will be adequately contained at all times during its existence (manufacture, storage, transport, use, and disposal) to prevent environmental release and human exposure.

2.3 Skin Irritation

(a) It is not technically feasible to administer the substance topically.

(b) The substance has a demonstrated pH of 2 or less or 11.5 or more, or demonstrated chemical reactivity likely to cause skin irritation.

(c) The substance has demonstrated high acute dermal toxicity; therefore, administration of the substance in accordance with the test protocol for skin irritation would cause excessive animal deaths (e.g., >25%).

(d) The substance was found to be an irritant in an acute dermal toxicity study.

2.4 Skin Sensitization

(a) It is not technically feasible to administer the substance topically.

(b) The substance is corrosive or highly irritating; therefore, administration of the substance in accordance with the test protocol for skin sensitization would cause severe and enduring pain to the test animals, and/or obscure any skin sensitization reaction.

2.5 Mutagenicity Tests

2.5.1 In Vitro *Gene Mutation*

(a) The chemical properties or physical form of the substance preclude(s) the adequate conduct of the test.

(b) An *in vitro* mammalian chromosomal aberration assay indicates that the substance has mutagenic activity.

(c) An *in vivo* mammalian genotoxicity assay indicates that the substance has mutagenic activity.

2.5.2 In Vitro *Mammalian Chromosomal Aberration*

(a) The chemical properties or physical form of the substance preclude(s) the adequate conduct of the test.

(b) An *in vitro* gene mutation assay indicates that the substance has mutagenic activity.

(c) An *in vivo* mammalian genotoxicity test indicates that the substance has mutagenic activity.

2.5.3 **In Vivo *Mammalian Mutagenicity Test***

(a) The chemical properties or physical form of the substance preclude(s) the adequate conduct of the test.

(b) The substance will be adequately contained at all times during its existence (manufacture, storage, transportation, use, and disposal) to prevent environmental release and human exposure.

(c) (1) the results of both the *in vitro* gene mutation and the *in vitro* mammalian chromosomal aberration tests indicate that the substance has no mutagenic activity;

(2) the intended use of the substance will not involve direct, repeated, or prolonged human exposure; and

(3) the chemical structure of the substance, or part thereof, is not related to a known mutagen or carcinogen.

3. Ecotoxicological Data

(a) The chemical properties or physical form of the substance preclude(s) the adequate conduct of the test.

Appendix 6 - Polymer/Biopolymer Test Methods

1. Number-average Molecular Weight (M_n)

1.1 Introduction

Molecular weight is the physical parameter that is typically used to describe the size of a polymer. Polymers/biopolymers consist of chains having varying lengths and varying molecular weights. Thus, a typical polymer/biopolymer has a distribution of molecular weights that can be depicted as a frequency distribution curve. Several mathematical moments can be described for such a curve and the first moment is called the number-average molecular weight (M_n). This parameter is very sensitive to the presence of small molecules in the polymer/biopolymer mixture. The second moment of the frequency distribution curve is called the weight-average molecular weight (M_w) and depends more on the number of heavier molecules present. The M_w values are related to bulk properties of the polymer/biopolymer associated with large deformations, such as viscosity and toughness. The ratio of M_n/M_w is called the polydispersity index and can be used to describe the molecular weight heterogeneity of polymers/biopolymers. A third moment, called the z-average molecular weight, can be related to the melt elasticity of the polymer/biopolymer. Therefore, several measures of polymer/biopolymer molecular weight can be made depending on which of the properties of the polymer/biopolymer are of interest. For environmental and toxicological assessment purposes, M_n is important because it is most closely related to the thermodynamic properties of the polymer/biopolymer, which control the degree to which the substance can be dissolved or transported in the environment.

The M_n is related to the colligative properties of the polymer/biopolymer molecule and can be determined by several different methods that measure such properties. These include: ebulliometry (elevation of boiling point); osmometry (both membrane and vapour pressure); and cryoscopy (depression of freezing point). Other methods for measuring M_n include: end-group analysis, and gel permeation chromatography (also known as size-exclusion chromatography). The latter technique is currently the method of choice for a wide range of polymers/biopolymers.

No single procedure is applicable over the entire range of polymer/biopolymer molecular weights. The choice of procedure is determined by the type of polymer/biopolymer being investigated and its molecular weight range.

1.2 Ebulliometry

(a) This is a classical method that measures the change in boiling temperature of a solvent caused by introduction of a soluble and non-volatile material.

(b) The method can measure M_n over the range of 500 to 20 000 daltons routinely, and up to 100 000 daltons with very sensitive apparatus and careful technique. Precision ranges from 1 to 5% at low molecular weights to 10 to 15% at high molecular weights.

(c) Determination of boiling point elevation at several concentrations and extrapolation to zero concentration (infinite dilution) is required to satisfy requirements for an ideal solution where polymer-polymer interactions are at a minimum.

(d) For discussion of the technique, apparatus, and precautions see Bonnar *et al.* (1958) and Glover (1966).

1.3 Cryoscopy

(a) This is a classical method, similar to ebulliometry, that measures the change in freezing temperature of a solvent caused by introduction of a soluble and non-volatile material.

(b) The method can measure M_n over the range of 500 to 20 000 daltons with a precision of 5 to 10%.

(c) Determination at several concentrations and extrapolation to zero concentration (infinite dilution) is required to satisfy the requirements for an ideal solution.

(d) For techniques, apparatus, and precautions, see Bonnar *et al.* (1958).

1.4 Osmometry

(a) Two osmometry techniques are currently used to determine polymer/biopolymer molecular weights. These are membrane osmometry and vapour pressure osmometry.

1.4.1 Membrane Osmometry

(a) In this method, the hydrostatic pressure necessary to maintain isothermal equilibrium between a solution of the sample on one side of a semi-permeable membrane, and the pure solvent on the other side of the membrane, is measured.

(b) The method can routinely measure M_n over the range of 15 000 to 500 000 daltons with a precision of 1 to 10%. With special apparatus and a suitable choice of membrane materials, a range up to 4 000 000 daltons can be achieved.

(c) Polymer/biopolymer samples with a broad range of molecular weights can cause problems with this technique because of solute permeation of the osmometer membrane by the low molecular weight fractions of the polymer/biopolymer. Suitable calibration and blank determinations can be used to alleviate this problem.

(d) Determination at several concentrations and extrapolation to infinite dilution conditions is required.

1.4.2 Vapour Phase Osmometry

(a) This is currently a popular method of determining absolute values of M_n for molecular weights up to 20 000 daltons.

(b) This technique does not use a membrane. A drop of polymer/biopolymer solution and a drop of solvent are placed on adjacent thermistors. The difference in solvent activity brings about a distillation of solvent from the solvent bead to the solution. The temperature change that results from the differential evaporation and condensation can be calibrated in terms of the number-average molecular weight of the polymer/biopolymer solute.

(c) The method is rapid, however, determination at multiple concentrations and extrapolation to infinite dilution are still required.

(d) Recommended methodology: ASTM D3750, Membrane Osmometry; ASTM D3592 (pre-1989), Vapour Pressure Osmometry.

1.5 End-group Analysis

(a) In this method, the concentration of characteristic end-groups in a polymer/biopolymer is determined using a suitable chemical or physicochemical method and, from this, a value for M_n can be estimated.

(b) The method is normally used to estimate M_n up to 25 000 daltons in polymers/biopolymers, with a precision of about 5%.

(c) The method applicability and precision normally depend on the type of sample, and often it is necessary to tailor the analysis method to the individual sample.

(d) Examples of typical methods include the determination of molecular weights for polyethylene terephthalate by titration of carboxylic and hydroxyl (converted to carboxylic) end-groups; polythioamides by ultraviolet (UV) spectroscopy of amine and thioester end-groups; polyvinyl acetate by titration of carboxyl end-groups; polyesters by infrared (IR) spectrophotometry of hydroxyl groups; and polyether polyols and hydroxyl end-capped polystyrene by nuclear magnetic resonance (NMR) spectroscopy of the hydroxyl group hydrogen (ASTM D4273).

1.6 *Gel Permeation Chromatography (GPC)*

(a) This method is currently the most widely used to determine polymer/biopolymer molecular weights.

(b) A solution of the sample in a suitable solvent is injected onto a column packed with a porous gel material of various pore sizes that separates sample molecules according to their effective sizes in solution (their hydrodynamic volumes). Molecules too large to penetrate any of the pores are not retained by the column packing and elute first. Molecules small enough to penetrate any or all of the pores are retained on the column and elute later. After injection of the sample solution onto the column, the hydrodynamic volume of the retained species eluted decreases logarithmically with increasing time. By injecting samples of known molecular weights (standards), the retention times or retention volumes of the observed peaks for each sample molecule can be correlated to specific molecular weights. This correlation becomes the basis of molecular weight calibration and allows the molecular weight of an unknown sample to be calculated in relation to a known standard. The detector response gives a measure of the amount of a particular molecular weight species in the sample. From a knowledge of the detector response and the calibration, M_n can be calculated.

(c) The technique requires the use of standards, usually commercially available. There may not be standards available for the analysis of certain polymer/biopolymer types. A standardization technique called "universal calibration" can often be used for these polymers/ibopolymers. The universal calibration technique, however, should be used with caution because it depends on a relationship between the hydrodynamic volume of the polymer/biopolymer molecule of interest and the product of its molecular weight and intrinsic viscosity. The constants in this relationship, known as Mark-Houwink constants, are determined by independent methods, and can be very sensitive to small variations in the GPC experimental parameters such as baseline uncertainties and interactions other than steric exclusion between the sample polymer/biopolymer and the separating gel. These variations can, in turn, create large errors in the calculated molecular weights for the polymer samples. Significant variations are also found in the literature for Mark-Houwink constants for particular polymers, depending on the method by which they were determined.

(d) The type of solvent used in the analysis is very important. Some samples may not be soluble in a solvent suitable for use in GPC.

(e) The technique has limitations due to adsorption, ion inclusion and related affinity effects, and ion exclusion. These effects can give false indications of molecular weights unless calibration is done with polymers/biopolymers of the same type as the one in which the affinity effect is being observed.

(f) Copolymers are difficult to analyze because the molecular size of random and block copolymers of the same molecular weight and comonomer composition in solution may not be the same. In addition, the detector response within the same molecular weight range may not vary linearly with the change in comonomer composition.

(g) Molecular weights obtained are not absolute values.

(h) The method can be applied over the whole range of polymer/biopolymer molecular weights as long as suitable solvents and standards are available.

(i) An example of a recommended methodology is ASTM D3593-08.03.

2. *Concentrations of Residual Constituents with Molecular Weights Less than 500 daltons and Less than 1000 daltons*

2.1 *Introduction*

Residual constituents include both polymer additives and low molecular weight oligomers. Several techniques can be used to identify and quantify these constituents and, in some cases, a combination of techniques may be required to identify all residuals. These techniques include: gel permeation chromatography (GPC); high performance liquid chromatography (HPLC); gas chromatography (GC), which may include the use of headspace sampling techniques, derivitization, and special detectors such as mass spectrometric detectors and infra-red detectors; supercritical fluid chromatography (SFC); spectroscopy; and chemical analysis. The most commonly used of these techniques for the analysis of residual constituents will be discussed.

The two most common detectors used in GPC and HPLC are refractive index (RI) and ultraviolet (UV) detectors. Each of these can be used to determine the concentration of residual components or oligomers that are absolutely homogeneous. However, many polymer/biopolymer products have heterogeneous molecular structures, i.e., they may be random block or graft copolymers or blends of polymers. As neither the RI nor the UV detector is mass sensitive, quantitation of heterogeneous components can be in error by several orders of magnitude. Flame ionization detectors, which are commonly used in both GC and SFC, are mass sensitive and are thus more widely applicable.

2.2 *Gel Permeation Chromatography (GPC)*

(a) The method can be used either to analyze constituents directly or as a fractionation technique for further analysis by other techniques.

(b) GPC is particularly applicable to the analysis of low molecular weight oligomers. These will be eluted after the normal polymer/biopolymer fractions and, depending on the conditions used and the type of polymer, some separation may be observed.

(c) The normal limitations of the GPC technique apply, including ion exclusion, ion inclusion, and ion affinity effects.

(d) When GPC is used to analyze for residual constituents rather than for monomer or low molecular weight oligomers, care should be taken to ensure that the components of interest do not co-elute with the polymer/biopolymer fractions. Because a residual constituent may be an entirely different chemical from the bulk polymer/biopolymer, any external calibration based on the polymer/biopolymer material itself will not be valid for quantitation of the residual chemical.

(e) GPC has been successfully applied to the analysis of residual isocyanates in urethane adhesives, styrene in copolymers, plasticizer in polystyrene, and phosphite and epoxide stabilizers in polystyrene and polyvinyl chloride.

(f) The method has been used as a pre-fractionation technique for subsequent fraction analysis by capillary GC or by HPLC.

2.3 High Performance Liquid Chromatography (HPLC)

(a) This technique is probably the most generally applicable to the analysis of residual components, both additives and low molecular weight oligomers.

(b) Both UV and RI detectors are commonly used, neither of which is mass sensitive; therefore, the technique is subject to the limitations described earlier. Although flame ionization detectors have been developed for HPLC, they are not generally used and have some severe limitations in this application.

(c) The technique is most applicable to the analysis of residual additives. Some described methods fractionate the sample by GPC prior to analysis of the fractions by HPLC.

(d) HPLC can be coupled to MS and IR for identification of the residual compounds.

2.4 Gas Chromatography (GC)

(a) The technique is generally only applicable to the analysis of residual additives, although some low molecular weight oligomers have been analyzed with suitable derivatization.

(b) GC can be used with dynamic headspace sampling techniques to avoid solvent extraction procedures.

(c) Derivatization is often required to make samples volatile enough for analysis by GC.

(d) Both packed and capiliary column analyses have been described for this application. However, capillary column GC is the most efficient for a wide range of compounds.

(e) GC can be coupled to MS or IR for identification of the sample compounds.

(f) The most commonly used GC detector is the flame ionization detector, which is mass sensitive. Therefore, some compounds that are difficult to analyze can be determined using this method.

2.5 Supercritical Fluid Chromatography

(a) This is a relatively new analytical technique; therefore, few methodologies are reported in the literature. However, the technique has the potential to be applied to the analysis of a wide range of compounds with low volatility.

(b) Supercritical Fluid Chromatography (SFC) uses flame ionization detection and can be coupled to MS or IR instruments.

(c) Supercritical fluid extraction can be used to introduce the sample to the chromatograph. This technique uses relatively mild conditions and, therefore, sample loss and degradation are minimized.

2.6 Spectroscopy

(a) A suitable sample extraction step is required.

(b) Any of the techniques of ultraviolet (UV) spectrophotometry, infrared (IR) spectrophotometry, nuclear magnetic resonance (NMR) spectroscopy, and mass spectrometry (MS) can be used to obtain qualitative and/or quantitative information on residual chemicals.

(c) Most of these techniques require a pre-separation step, usually by a form of chromatography (e.g., column, TLC, GC, HPLC).

3. *Water Solubility*

3.1 *Introduction*

Water solubility should be determined on the notified polymer/biopolymer, however, it is recognized that a representative sample of the notified substance may not be available at the time of testing. Before the water solubility is determined, the sample on which testing is to be carried out should be prepared to make it as similar as possible to the notified polymer/biopolymer. For example, residual solvent should be removed. This may be accomplished by subjecting the sample to an initial water extraction, by heating the sample, or by using a vacuum apparatus.

3.2 *Methods*

(a) Determination of solubility at pH 7. One suitable method is OECD Guideline 105.

(b) Determination of solubility at pH 1 and 10. One suitable method is to modify OECD Guideline 105 by using hydrochloric acid to adjust to pH 1 or, for solubility at pH 10, by using sodium or potassium hydroxide to adjust to the desired pH (CEC Annex V methodology).

(c) For consistency in analytical procedures, and in the accuracy and precision of the results obtained, the flask method of water solubility determination is the preferred choice.

(d) The water soluble portion can be analyzed directly, or after solvent extraction and concentration, by chromatographic or spectroscopic techniques. Any components in this residue that can be identified as additives should be discounted for the purpose of determining the solubility of the polymer/biopolymer itself.

4. *Solubility in* n*-Octanol and Octanol-Water Partition Coefficient*

4.1 *Introduction*

Tests for solubility in *n*-octanol and the octanol-water partition coefficient should be carried out on the notified substance or on a sample that has been prepared to be representative of the notified substance. See water solubility for details.

(a) A recommended procedure is to modify the flask method (described in OECD Guideline 105) by using analytical grade n-octanol as the solvent and by running the determination at 20 °C.

(b) The *n*-octanol extract should be analyzed directly for the dissolved polymer/biopolymer by a suitable method; or the *n*-octanol should be evaporated under reduced pressure and the residue analyzed for the polymer/biopolymer, again by a suitable method. For the aqueous solubility tests, any components identified as additives should be discounted to determine the true solubility of the polymer/biopolymer itself.

(c) Recommended methods for the determination of the octanol-water partition coefficient are OECD methods 107 and 117.

5. *Hydrolysis as a Function of pH*

(a) A recommended method is OECD Guideline 111.

(b) It is also required that, if the products of hydrolysis are known, they should be identified by a suitable technique. Suggested methods include solvent extraction of the product followed by concentration and analysis by GC, HPLC, spectroscopy, or appropriate chemical analysis.

6. *Ultraviolet - Visible Spectrum*

(a) The purpose of this test is to provide an indication of the photochemical stability of the polymer/biopolymer by measuring its absorbance in the region of solar incident radiation from a wavelength of 290 to 700 nm.

(b) A recommended procedure (devised by the U.S. EPA Office of Toxic Substances) measures the spectrum of a solution of the polymer/biopolymer in a suitable non-associative solvent (e.g., hexane, cyclohexane, carbon tetrachloride, or methylene chloride) over the wavelength range of 290 to 700 nm. Because solvent effects cannot be predicted, determinations with solutions in at least two solvents that result in the same absorption spectrum should be made.

7. *Ready Biodegradability*

(a) The recommended method is OECD Guideline 301. Only Guidelines 301B, 301C, and 301D are suitable for the analysis of insoluble substances.

8. *References*

(a) Bonnar, R.U., M. Dimbat, and F. H. Stross, *Number-Average Molecular Weights - Fundamentals and Determination*, Interscience, New York, NY (1958).

(b) Glover, C.A. "Determination of Molecular Weights by Ebulliometry," In *Advances in Analytical Chemistry and Instrumentation*. Volume 5. Reilley, C.N. and F. W.

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McLafferty, (eds.) Interscience, New York, NY (1966).

Appendix 7 - Masking of Substance Names

The procedures presented below are based on guidelines developed by the U.S. EPA for purposes of the TSCA inventory. They have been modified for Canadian use and are included to provide guidance to persons submitting New Substances Notifications and wishing to claim specific identities as confidential. Consequently, a masked name must be submitted for publication purposes. The intent of masking is to disguise, only to the extent necessary, the full identity of the substance. Although this appendix illustrates the masking of only a single structural feature, multiple masking is permitted if the notifier can provide justification.

There are inherent differences between naming substances with a definite chemical structure and naming substances that cannot be depicted by a structural diagram. Each of these possibilities is addressed separately.

1. Substances Having a Definite Chemical Structure

Substances having a definite chemical structure can be represented by a unique structure diagram. The names of substances with a distinct chemical identity normally disclose the following structural information:

(a) the identity of parent structure (i.e., a chain of carbon atoms, a ring system, or a coordinated metal);

(b) the identity, number, and position of chemical group(s) that are attached to the parent structure(s) or to other chemical groups;

(c) the identity and number of counter ions (for salts); and

(d) the stereochemical relationships.

Masked names may be created for substances with a distinct chemical identity by disguising structurally descriptive segments of the specific chemical name. Masking may be accomplished by substituting non-descriptive terms for distinctive parts of the name. Proposed masked names created by eliminating stereochemical indicators (if appropriate) from the specific chemical name and by masking one other structure detail will, in most cases, be acceptable to Environment Canada.

The structurally descriptive parts of a chemical name that could be masked when creating a proposed name are:

(a) a locant that specifies the placement of a single chemical group;

(b) the locant and multiplicative prefixes (e.g., di-,tri-, and tetra-) that together specify the number and placement of a given chemical group;

(c) the identity (but not placement and number) of a given chemical group;

(d) the identity of a given parent structure, and locants of a substituent chemical group; and

(e) the identity and multiplicative prefixes (specifying the number) of a given simple cation or anion of a salt.

Table 11 lists by name and molecular formula the type of chemical groups that can be masked. The groups of atoms found in Table 11 are common structural units; a given group may be listed under more than one name. Each group includes at least one atom other than carbon or hydrogen.

A chemical group that includes a carbon atom having more than one single free valence (e.g., carbonyl -CO-) cannot be masked if the carbon is directly attached to an acyclic carbon atom or is included within a ring system; in this circumstance, only the atom or group of atoms attached to the carbon atom can be masked (see Example 2, where the oxo group is masked).

Certain chemical groups in Table 11 include hydrogen atoms that are often additionally substituted, e.g., an ethyl group may be substituted for a hydrogen of the sulfamyl group (H_2NSO_2-) to give $C_2H_5NHSO_2$-. If additionally substituted, **only** the chemical group listed in Table 11 should be masked, **not** the substituent.

Table 11 lists most of the common chemical functional groups that contain oxygen, e.g., H_2NCO-. Although not always listed, the Group VIa element (sulfur, selenium, and tellurium) analogs of these functional groups, e.g., H_2NCSe-, are considered included within Table 11 and, accordingly, may be used in masking.

Table 11 List of Common Chemical Structural Units

aldo O=
amidino $H_2NC(=NH)$-
amino H_2N-
(aminoamidino) $H_2NC(=NNH_2)$- or $H_2NNHC(=NH)$-
(aminocarbonyl) H_2NCO-
[(aminocarbonyl)amino] H_2NCONH-
[2-(aminocarbonyl)hydrazino] $H_2NCONHNH$-
[(aminocarbonyl)hydrazono] $H_2NCONHN$=
(aminohydrazonomethyl) $H_2NC(=NNH_2)$-
[(aminohydroxymethylene) hydrazino] $H_2NC(OH)=NNH$-
(aminoiminomethyl) $H_2NC(=NH)$-

Table 11 *(continued)*   List of Common Chemical Structural Units

(aminoiminophosphoranyl) $H_2NPH(=NH)-$

(P-aminophosphinimyl) $H_2NPH(=NH)-$
(aminosulfinyl) H_2NSO-
(aminosulfonyl) H_2NSO_2-
(aminothio) H_2NS-
(aminothioxomethyl) H_2NCS-
ammonio H_3N-
antimono $-Sb=Sb-$
arseno $-As=As-$
arsenoso $OAs-$
arsinico $HOAs(O)\equiv$
arsinidene $AsH=$
arsinidyne $As\equiv$
arsinimyl $AsH_2(=NH)-$
arsino AsH_2-
arsinothioyl $AsH_2(S)-$
arsinyl $AsH_2(O)-$
arsinylidene $AsH(O)\equiv$
arso O_2As-
arsono $(HO)_2As(O)-$
(arsonooxy) $(HO)_2As(O)O-$
arsononitridyl $AsH(=N)-$
arsoranyl AsH_4-
arsoranylidyne $AsH_2\equiv$
arsylene $AsH=$
arsylidyne $As\equiv$
astato $At-$
astatoxy O_2At-
astatyl O_2At-
azi $-N=N-$
azido N_3-
(azidocarbonyl) N_3CO-
(azidofurmyl) N_3CO-
(azidosulfonyl) N_3SO_2-
azino $=NN=$
azo $-N=N-$
azoxy $-N(O)=N-$

bismuthino BiH_2-
bismuthylene $BiH=$
bismuthylidyne $Bi\equiv$
borono $(HO)_2B-$

Table 11 (*continued*) List of Common Chemical Structural Units

(boronooxy) $(HO)_2BO-$
boryl BH_2-

borylene BH=
borylidyne B≡
bromo Br-
(bromocarbonyl) BrCO-
(bromoiminomethyl) BrC(=NH)-
(bromosulfonyl) $BrSO_2-$

carbamido $H_2NCONH-$
carbamoyl H_2NCO-
carbamyl H_2NCO-
carbonimidoyl -C(=NH)=
(carbonimidoylamino) $H_2N=C=N-$
carbonothioyl -CS-
carbonyl -CO-
(carbonylidiimino) -NHCONH-
(carbonyldioxy) -OC(O)O-
carboxy HO_2C-
chloro Cl-
(chlorocarbonyl) ClCO-
(chloroformyl) ClCO-
(chloroiminomethyl) ClC(=NH)-
(chlorosulfinyl) ClSO-
(chlorosulfonyl) $ClSO_2-$
chlorosyl OCl-
(chlorothio) ClS-
chloryl O_2Cl-
cyanato NCO-
cyano NC-

1,2-diarsenediyl -As=As-
diarsenyl HAs=As-
diarsinetetrayl =AsAs=
diarsinyl $H_2AsAsH-$
1,2-diazenediyl -N=N-
diazeno HN=N-
diazo $N_2=$
diazoamino -NHN=N-
diazonio N_2^+-
1,2-diborane(4)diylidene =BB=
diborane(4)tetrayl =BB=

Table 11 (*continued*) List of Common Chemical Structural Units

digermanylene $\mathrm{-GeH_2GeH_2-}$
digermathianyl $\mathrm{H_3GeSGeH_2-}$
dioxy -OO-
1,2-diphosphenediyl -P=P-
1,2-diphosphinediyl -PHPH-
1,2-diphosphinediylidene =PP=
diphosphinetetrayl =PP=
diphosphinyl $\mathrm{H_2PPH-}$
diseleno -SeSe-
1,2-disilanediyl $\mathrm{-SiH_2SiH_2-}$
disilanoxy $\mathrm{H_3SiSiH_2O-}$
disilanyl $\mathrm{H_3SiSiH_2-}$
disilanylene $\mathrm{-SiH_2SiH_2-}$
(disilanyloxy) $\mathrm{H_3SiSiH_2O-}$
(disilathianyloxy) $\mathrm{H_3SiSSiH_2O-}$
disilazanoxy $\mathrm{H_3SiNHSiH_2O-}$
disilazanyl $\mathrm{H_3SiNHSiH_2-}$
2-disilazanyl $\mathrm{(H_3Si)_2N-}$
(disilazanyloxy) $\mathrm{H_3SiNHSiH_2O-}$
1,3-disiloxanediyl $\mathrm{-SiH_2OSiH_2-}$
1,3-disiloxanediylidene =SiHOSiH=
disiloxanoxy $\mathrm{H_3SiOSiH_2O-}$
disiloxanylene $\mathrm{-SiH_2OSiH_2-}$
(disiloxanyloxy) $\mathrm{H_3SiOSiH_2O}$
disilthianoxy $\mathrm{H_3SiSSiH_2O-}$
1,2-distannanediyl $\mathrm{-SnH_2SnH_2}$
distannanylene $\mathrm{-SnH_2SnH_2-}$
1,3-distannathianediylidene =SnHSSnH=
1,2-distibenediyl -Sb=Sb-
disulfinyl -S(O)S(O)-
dithio -SS-
(dithiocarboxy) HSCS-
(dithiohydroperoxy) HSS-

epidioxy -OO-
epidiseleno -SeSe-
epidithio -SS-
epioxy -O-
episeleno -Se-
epithio -S-
epoxy -O-

fluoro F-

Table 11 (*continued*) List of Common Chemical Structural Units

(fluorocarbonyl) FCO-
fluoryl O_2F-
formamido HCONH-
1,5-formazanidyl -N=NCH=NNH-
1-formazano H_2NN=CHN=N-
5-formazano HN=NCH=NNH-
formazanyl HN=NC(=NNH_2)-
formimidoyl HC(=NH)-
formyl HCO-
(formylamino) HCONH-

germanetetrayl =Ge=
germyl H_3Ge-
germylene H_2Ge=
germylidyne HGe≡
guanyl H_2NC(=NH)-

hydrazi -NHNH-
1,2-hydrazinediylidene =NN=
hydrazino H_2NNH-
(hydrazinocarbonyl) H_2NNHCO-
(hydrazinoiminomethyl) H_2NNHC(=NH)-
(hydrazinosulfinyl) H_2NNHSO-
(hydrazinosulfonyl) H_2NNHSO_2-
(hydrazinothioxomethyl) H_2NNHCS-
1-hydrazinyl-2-ylidene -NHN=
hydrazo -NHNH-
hydrazono H_2NN=
hydroperoxy HOO-
(hydroperoxycarbonyl) HOOCO-
(hydroperoxyiminomethyl) HOOC(=NH)-
(hydroperoxysulfinyl) HOOS(=O)-
(hydroperoxysulfonyl) HOOS$(=O)_2$-
(hydroperoxythioxomethyl) HOOCS-
hydroxy HO-
(hydroxyamino) HONH-
(hydroxyimino) HON=
(hydroxyiminomethyl) HOC(=NH)-
hydroxyl HO-
(hydroxyphosphinyl) HOPH(O)-

imidocarbonyl -C(=NH)-
(imidocarbonylamino) HN=C=N-

Table 11 (*continued*) List of Common Chemical Structural Units

imino HN=
(iminomercaptomethyl) HSC(=NH)-
[imino(mercaptooxy)methyl] HSOC(=NH)-
(iminomethyl) HN=CH-
(iminonitrilo) -NHN=
(iminophosphoranyl) $H_2P(=NH)$-
(iminosulfenomethyl) HOSC(=NH)-
iodo I-
(iodocarbonyl) ICO-
iodosyl OI-
iodyl O_2I-
isocyanato OCN-
(isocyanatocarbonyl) OCNCO-
(isocyanatosulfonyl) $OCNSO_2$-
isocyano CN-
(isocyanocarbonyl) CNCO-
isonitro HON(O)=
isonitroso HON=
isosemicarbazido $H_2NC(OH)=NNH$-
isothiocyanato SCN-
(isothiocyanatocarbonyl) SCNCO-
(isothiocyanatosulfonyl) $SCNSO_2$-
isothiocyano SCN-

Keto O=

mercapto HS-
(mercaptoamino) HSNH-
(mercaptooxy) HSO-
[(mercaptooxy)carbonyl] HSOCO-
[(mercaptooxy)sulfinyl] HSOS(=O)-
[(mercaptooxy)sulfonyl] $HSOS(=O)_2$-
[(mercaptooxy)thioxomethyl] HSOCS-
(mercaptotelluro) HSTe-

nitramino O_2NNH-
aci-nitramino HON(O)=N-
nitrilio $HN^+\equiv$
nitrilo $N\equiv$
(nitrilophosphoranyl) HP(=N)-
nitro O_2N-
acinitro HON(O)=
(nitroamino) O_2NNH-

Table 11 (*continued*) List of Common Chemical Structural Units

(*aci*-nitroamino) HON(O)=N-
(nitrooxy) O_2NO-
nitroso ON-
(nitrosoamino) ONNH-
(nitrosoimino) ONN=
(nitrosooxy) ONO-
(nitrothio) O_2NS-

oximido HON=
oxo O=
(oxoboryl) OB-
oxy -O-

1,3-pentazadienyl $H_2NN{=}NN{=}N$-
perchloryl O_3Cl-
perseleno Se=Se=
perthio S=S=
phosphinico HOP(O)=
phosphinidene HO=
phosphinidyne P=
phosphinimyl $H_2P({=}NH)$-
phosphino H_2P-
phosphinothioyl $H_2P(S)$-
phosphinothioylidene HP(S)=
phosphinyl $H_2P(O)$-
phosphinylidene HP(O)=
phosphinylidyne P(O)=
phospho O_2P-
phosphono $(HO)_2P(O)$-
(phosphonocarbonyl) $(HO)_2P(CO)$
phosphononitridyl HP(=N)-
(phosphonooxy) $(HO)_2P(O)O$-
phosphoranyl H_4P-
phosphoranylidene H_3P=
phosphoranylidyne $H_2P\equiv$
phosphoro -P=P-
phosphoroso OP-
plumbanetetrayl =Pb=
plumbyl H_3Pb-
plumbylene H_2Pb=
plumbylidyne HPb=

seleneno HOSe-

Table 11 (*continued*) List of Common Chemical Structural Units

selenino $HOSe(O)-$
seleninoselenoyl $Se{=}Se{=}$
seleninyl $OSe{=}$
seleno $-Se-$
selenocyanato $NCSe-$
selenono $(HO)SeO2-$
selenonyl $O_2Se{=}$
selenoxo $Se{=}$
selenyl $HSe-$
semicarbazido $H_2NCONHNH-$
semicarbazono $H_2NCONHN{=}$
silanetetrayl $={Si}=$
silyl H_3Si-
silylene $H_2Si{=}$
silylidyne $HSi\equiv$
(silyloxy) H_3SiO-
stannanetetrayl $={Sn}=$
stannono $HOSn(O)-$
stannyl H_3Sn-
stannylene $H_2Sn{=}$
stannylidyne $HSn\equiv$
stibinico $HOSb(O){=}$
stibino H_2Sb-
stibo O_2Sb-
stibono $(HO)_2Sb(O)-$
(stibonooxy) $(HO)_2Sb(O)O-$
stiboso $OSb-$
stibyl H_2Sb-
stibylene $HSb{=}$
stibylidyne $Sb\equiv$
sulfamino $HOSO_2NH-$
sulfamoyl H_2NSO_2-
sulfamyl H_2NSO_2-
sulfeno $HOS-$
(sulfenocarbonyl) $HOSCO-$
(sulfenosulfinyl) $HOSS({=}O)-$
(sulfenosulfonyl) $HOSS({=}O)_2-$
(sulfenothioxomethyl) $HOSCS-$
sulfhydryl $HS-$
sulfinimidoyl $HN{=}S{=}$
sulfino $HOS(O)$
(sulfinooxy) $HOS(O)O-$
sulfinothioyl $S{=}S{=}$

Table 11 (*continued*) List of Common Chemical Structural Units

sulfinyl OS=
sulfo HO_3S-
(sulfoamino) $HOSO_2NH$-
sulfonimidoyl HN=S(O)=
sulfonodiimidoyl $(HN=)_2S$=
sulfonyl -SO_2-
(sulfooxy) HO_3SO-
sulfuryl -SO_2-

telluro -Te-
telluroxo Te=
telluryl HTe-
1,4-tetraphosphinediyl -$(PH)_4$-
1,7-tetrasiloxanediyl -$SiH_2(OSiH_2)_2OSiH_2$-
tetrathio -SSSS-
1,4-tetrazanediyl -$(NH)_4$-
1,4-tetrazanediylidene =$N(NH)_2N$=
1-tetrazenyl H_2NNHN=N-
thio -S-
(thioarsenoso) S=As-
(thiocarbamoyl) H_2NCS-
thiocarbamyl H_2NCS-
(thiocarbonyl) -CS-
(thiocarboxy) HOSC-
thiocyanato NCS-
thiocyano NCS-
(thioformyl) HCS-
thiohydroperoxy HOS- or HSO-
(thiohydroxy) HS-
(thionitroso) SN-
thionyl -SO-
(thioseleneno) HSSe-
(thiosulfeno) HSS-
(thiosulfo) (HO_2S_2)-
thioxo S=
(thioxoarsino) S=As-
(thioxomethyl) HCS-
thiuram H_2NCS-
triazanyl H_2NNHNH-
1-triazene-1,3-diyl -NHN=N-
1-triazenyl H_2NN=N-
triseleno -SeSeSe-
1,3-trisilanediyl -$(SiH_2)_3$-

Table 11 (*continued*) **List of Common Chemical Structural Units**

1,3,5-trisiloxanetriyl $-SiH(OSiH_2-)_2$
trithio -SSS-

uramino $H_2NCONH-$
ureido $H_2NCONH-$
ureylene -NHCONH-

1.1 *Parent Masking*

A parent structure that is a chain of carbon atoms or a ring system may be masked in the chemical name only by the following masked terms:

alkyl **or** alkane
alkenyl **or** alkene
alkynyl **or** alkyne
carbomonocyclic **or** carbomonocycle (e.g., benzene, cyclopentane)
carbopolycyclic **or** carbopolycycle (e.g., naphthalene, spiroundecane)
heteromonocyclic **or** heteromonocycle (e.g., pyrrole, *p*-dioxane)
heteropolycyclic **or** heteropolycycle (e.g., indole, benzothiazole)

In the case of a coordinated metal compound, the identity of the metal atom may be masked by the term "metal" in the chemical name.

Only one such parent group or multiple occurrences of the **same** parent group should be masked.

The following examples show how several hypothetical compounds could be identified by names that mask only **one** structural detail (other than stereochemistry).

1.1.1 *Example 1*

$$CF_3CF_2CF_2CF_2CF_2CH_2N(CH_2CH_2OH)_2$$

1.1.1.1 *Fully Defined Name*

2,2,3,3,4,4,5,5,6,6,6-undecafluoro-**N**,**N**-bis(2-hydroxyethyl) hexanamide

1.1.1.2 *Acceptable Masked Names*

- fluorine atoms masked:

  N,**N**-bis(2-hydroxyethyl)-2,2,3,3,4,4,5,5,6,6,6-undecahalosubstituted hexanamide

- number of fluorine atoms masked:

  polyfluoro-**N**,**N**-bis(2-hydroxyethyl)hexanamide

- hydroxyl groups masked:

  2,2,3,3,4,4,5,5,6,6,6-undecafluoro-**N**,**N**-bis(2-substituted ethyl) hexanamide

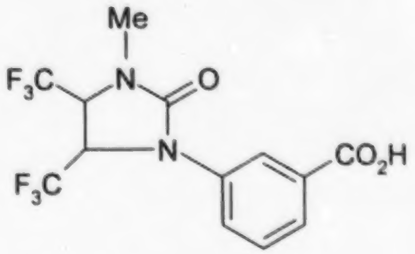
- hexane parent (plus locants) masked:

  undecafluoro-**N**,**N**-bis(2-hydroxyethyl)alkanamide

- amide group (plus nitrogen locants) masked:

  2,2,3,3,4,4,5,5,6,6,6-undecafluorobis(2-hydroxyethyl)hexane derivative

1.1.2 Example 2



1.1.2.1 Fully Defined Name

4-[3-methyl-2-oxo-4,5-bis(trifluoromethyl)-1-imidazolidinyl]benzoic acid

1.1.2.2 Acceptable Masked Names

- oxo group masked:

  4-[3-methyl-2-substituted-4,5-bis(trifluoromethyl)-1-imidazolidinyl]benzoic acid

  (NOTE: Only the oxo and not the carbonyl group has been masked.)

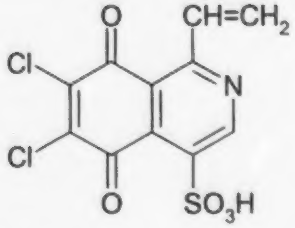
- fluorine atoms masked:

  4-[3-methyl-2-oxo-4,5-bis(trihalosubstituted methyl)-1-imidazolidinyl]benzoic acid

- imidazolidine ring (plus locants) masked:

  4-[methyloxobis(trifluoromethyl)heteromonocycle]benzoic acid

1.1.3 Example 3



1.1.3.1 Fully Defined Name

6,7-dichloro-1-ethenyl-5,8-dihydro-5,8-dioxo-4-isoquinolinesulfonic acid

1.1.3.2 Acceptable Masked Names

- chlorine atoms masked:

  1-ethenyl-5,8-dihydro-5,8-dioxo-6,7-dihalosubstituted-4-isoquinolinesulfonic acid

- vinyl group masked:

  1-alkenyl-6,7-dichloro-5,8-dihydro-5,8-dioxo-4-isoquinolinesulfonic acid

- oxo group masked:

  6,7-dichloro-1-ethenyl-5,8-dihydro-5,8-dihalosubstituted-4-isoquinoline sulfonic acid

- sulfo group masked:

  6,7-dichloro-1-ethenyl-5,8-dihydro-5,8-dioxo-4-substituted isoquinoline

- isoquinoline ring (plus locants) masked:

  dichloroethenyldihydrodioxo heteropolycyclic sulfonic acid or
  dichloroethenyldihydrodioxosulfo heteropolycycle

2. Substances Not Having A Definite Chemical Structure

Some substances can only be represented by partial or incomplete chemical structures; in other instances the composition can only be described in terms of a complex combination of several different known or unknown components.

The method of manufacture can also identify a substance. For a substance manufactured by a chemical reaction, identification can be stated in terms of the immediate precursor substances and other reactants that participate in the final reaction sequence used to manufacture the substance, and the nature of the reaction (e.g., ethoxylation or bromination). For a substance derived from a source without chemical reaction, processing information identifies the source and method of derivation (e.g., distillation, or extraction with methylene chloride).

Although the name of substances lacking a definite chemical structure may be based on variable types of information, the procedures similar to those used for substances with a definite chemical structure may be applicable.

The composition of a substance that can be represented by a partial or incomplete chemical structure diagram can generally be described by a common chemical name that encompasses the variability or incompleteness in the structure. A masked name for such a substance will usually be acceptable if the previous guidelines for substances with a definite chemical structure have been followed.

In other instances, the preferred name may identify a predominant component or components of its composition, an immediate precursor or precursors, and other reactants by specific chemical name. A proposed masked name will usually be acceptable for such a substance if it is constructed by masking the chemical name of **one** such component, precursor, or reactant.

Clearly, these guideline procedures are most useful for masking the identity of substances having a distinct chemical identity, and will only be useful for some types of substances that cannot be described with a chemical structure. In some of these latter cases, the guidelines provided may have little applicability. For consistency, submitters must base their choice of a masked name on a CAS Preferred Name. Environment Canada will consider each such proposed masked name on a case-by-case basis.

2.1 Example 4

2.1.1 Substance Description

Linseed-oil fatty acids-fumaric acid-glycerol-maleic anhydride polymer

2.1.2 Specific Chemical Name

Fatty acids, linseed-oil, polymers with fumaric acid, glycerol and maleic anhydride

2.1.3 Acceptable Masked Names

- linseed-oil masked:

  Fatty acids, polymers with fumaric acid, glycerol and maleic anhydride

- fumaric acid masked:

  Fatty acids, linseed-oil, polymers with alkenedioic acid, glycerol and maleic anhydride

2.2 Example 5

2.2.1 Substance Description

Reaction product of 1,8-dihydroxy-4,5-dinitro-9,10-anthracenedione with aniline and 2-chloroethanol

2.2.2 Specific Chemical Name

1,8-dihydroxy-4,5-dinitro-9,10-anthracenedione reaction products with aniline and 2-chloroethanol

2.2.3 Acceptable Masked Names

- hydroxyl groups masked:

  1,8-disubstituted-4,5-dinitro-9,10-anthracenedione reaction products with aniline and 2-chloroethanol

- anthracene parent (plus locants) masked:

  dihydroxydinitrodioxopolycycle reaction products with aniline and 2-chloroethanol

- chlorine atom masked:

  1,8-dihydroxy-4,5-dinitro-9,10-anthracenedione reaction products with aniline and 2-halosubstituted ethanol

2.3 Example 6

2.3.1 Substance Description

Polyethylene glycol, mono-C_{12-15}-alkyl ethers, phosphates, potassium salts

2.3.2 Specific Chemical Name

Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-, mono-C_{12-15}-alkyl ethers, phosphates, potassium salts

2.3.3 Acceptable Masked Names

- potassium salts masked:

  Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-, mono-C_{12-15}-alkyl ethers, phosphates, metal salts

- C_{12-15}-alkyl group masked:

  Poly(oxy-1,2-ethanediyl), α-hydro-ω-hydroxy-, monoalkyl ethers, phosphates, potassium salts

- 1,2-ethanediyl masked:

  Poly(oxyalkylenediyl), α-hydro-ω-hydroxy-, mono-$C_{12\text{-}15}$-alkyl ethers, phosphates, potassium salts

3. *Masking of Biochemicals and Biopolymers*

Biochemicals and biopolymers that do not have catalytic activity can be masked by disguising descriptive segments of the specific chemical name. Masking of more than one segment of the chemical name is considered multiple masking and would not be permitted without justification. Masking may be accomplished by substituting non-descriptive terms for distinctive parts of the chemical name. Please refer to Sections 1 and 2 above.

3.1 Enzymatic Substances

Masked names may be created for enzymes by disguising the fourth level IUBMB number description.

Example: substance reported:

Cholestenone 5β-reductase IUBMB number 1.3.1.22

Masked name that could be proposed:

$NADP^+$ oxidoreductase IUBMB number 1.3.1

In instances where a fourth level IUBMB number only consists of one entry, Environment Canada will accept reverting to the second level IUBMB number.

Example: substance reported:

6-Hydroxynicotinate reductase IUBMB number 1.3.7.1

Masked name that could be proposed:

Acceptor oxidoreductase IUBMB number 1.3

4. *Justifying the Use of Additional Masking*

Notifiers who determine that strict application of these guideline procedures would not adequately mask the confidential substance identity may propose a masked name that disguises the substance identity to a greater extent than provided for by these procedures. Such additional masking should be substantiated in a written statement accompanying the notification. The statement should be prepared in the following manner:

(a) Construct each reasonably applicable masked name developed following the described procedures.

(b) For each masked name constructed, discuss the reason why the name is inappropriate for publication purposes. For example, the number of substances encompassed by the masked name may be very small. Or, the masked name may still reveal information about the substance that in and of itself formed the basis for the confidential substance identity claim. These reasons should be clearly explained.

(c) Select a suitable masked name that disguises two aspects of the substance identity. If such double masking is still perceived as inappropriate, state the reason for rejecting each reasonably applicable doubly masked name before proceeding to propose a name that masks three or more aspects of the substance name.

Appendix 8 - Glossary

Acceptable to the Departments with respect to a test method means a method that enables a sufficient quantity and quality of data to be generated for a meaningful assessment of the end-point under investigation. Important considerations of the method include the use of standards and controls; detection limits; species selected; tissues investigated; doses; adherence to GLP; validation of the method; and, statistical power of the method (see also **Indicator of mutagenicity**).

Adequately contained means all precautions and measures necessary to prevent the release of the substance to the environment. With respect to the transportation of a substance, adequate containment requires full compliance with the *Transportation of Dangerous Goods Act*.

Anionic polymer/biopolymer means a polymer that contains one or more covalently linked monomer units that bear a net negative charge (see also **monomer unit, polymer**).

Assessment period means the number of calendar days that the government has to assess the information submitted by a notifier under the New Substances Notification Regulations (see also **notification period**).

Biochemical means a product of biotechnology, other than a living organism or a biopolymer, that is produced by a micro-organism.

Note: killed or dead micro-organisms are also considered biochemicals.

Biopolymer means a polymer produced by a micro-organism (see also **polymer**).

Biotechnology means the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms.

By-product means a substance produced without separate commercial intent during the manufacture of another substance.

Cationic polymer/biopolymer means a polymer that contains one or more covalently linked monomer units that bear a net positive charge (see also **monomer unit, polymer**).

Chemical, with respect to the New Substances Notification Regulations, means a substance that is neither a polymer nor a product of biotechnology (see also **biotechnology product, polymer**).

Consumed means the destruction of a substance or its complete conversion to another substance. "Complete conversion" implies that the reaction has proceeded to the point where no further conversion of the substance is likely under the reaction conditions.

Direct human exposure to a substance results from direct contact with, or close proximity to, the substance during any part of its life cycle (manufacture, processing and handling, storage, transportation, use, disposal) whether knowingly or not. Direct exposure to the substance occurs by the same environmental media into which the substance was released. This differs from indirect human exposure, which involves exposure to the substance in a medium different from that into which the substance was released.

Domestic Substances List (DSL) means the list compiled by the Minister of the Environment under subsection 66(1) of the CEPA, 1999, as amended from time to time by the Minister under subsection 66(3) or subsections 87(1) and (5) of the Act (see also **Non-domestic Substances List**).

Evidence that the tissue investigated was exposed to the substance or its metabolites with respect to the *in vivo* mutagenicity test in Schedule III and Schedule VIII is necessary to determine the appropriateness of the tissue(s) investigated in assessing the *in vivo* mutagenicity of a substance, and thus the adequacy of the test. This clause indicates the need for sufficient information to support a conclusion that the tissue investigated was exposed to the test substance or its metabolites. The strength of the evidence required will be balanced with the concern of the mutagenic potential of the substance, for example: results from *in vitro* mutagenicity tests; structure; potential for exposure; tissue investigated; and test method. Examples of what may constitute evidence of tissue exposure include:

(a) a positive result for the test endpoint in the tissue investigated;

(b) cytotoxicity observed in the tissue investigated, e.g., statistically significant reduction in the mitotic index, cell cycle delay, decrease in the ratio of polychromatic to normochromatic erythrocytes;

(c) general organ toxicity in the tissue investigated, e.g., significant change in organ weight or hyperplasia; and

(d) data from a tissue distribution study indicating the presence of the substance or its metabolites in the tissue investigated.

Impurity means a substance whose presence with another substance is not intentional, is not necessary to the end use of the product, and does not enhance the commercial value of the product.

Indicator of mutagenicity with respect to permitting an assessment of *in vitro* or *in vivo* mutagenicity means tests that are "acceptable to the Departments" for determining the *in vitro* or *in vivo* mutagenic potential of the substance. This wording is intended to permit the selection of the most appropriate test(s) for a substance, and to allow developments in the field of genotoxicity to quickly become part of a testing strategy. It is recommended that the investigator consult with Health Canada officials before testing to determine the acceptability of a test for that specific substance (see also **Acceptable to the Departments**).

In the person's possession means information in the company's offices in Canada or, if the notification was submitted by a foreign company through a Canadian agent, the offices in the country where the notification originated.

Intermediate substance means a substance that is consumed in whole or in part in a chemical reaction used for the intentional manufacture of other substances (see also **consumed, site-limited intermediate, transient reaction intermediate**).

Item means, with respect to the new substances provisions of the CEPA, 1999, any manufactured item formed into a specific physical shape or design during manufacture that has, for its final use, a function or functions that depend, in whole or in part, on its shape or design.

Masked name means a name based on CAS, IUPAC or IUBMB nomenclature, but having one or more of the specific components identified in a manner that prevents the identification of the specific chemical structure. Masking a substance name will only be acceptable to the extent necessary to disguise the full identity of the substance, while retaining the generic molecular structure.

Minister means the Minister of the Environment; whereas, Ministers means the Ministers of the Environment and of Health.

Monomer unit means the reacted form of a monomer in a polymer (see also **polymer**).

Most significant route of potential human exposure means exposure of the general population in Canada. Consideration should be given to the expected level of the substance in the various environmental media and consumer products, and the bioavailability of the substance by ingestion, inhalation, and dermal absorption, to select the most appropriate route (oral, inhalation, dermal) for testing. The most significant route of exposure to a substance for the general population may be different from exposures for workers in an occupational setting. Consequently, data generated for occupational exposures may not meet the requirement for the most significant route of potential human exposure specified in the Regulation.

Non-domestic Substances List (NDSL) means the list compiled by the Minister under subsection 66(2) of the CEPA, 1999, as amended from time to time by the Minister under subsection 66(3) or subsections 87(1) and (5) of the Act (see also **Domestic Substances List**).

Notification period means the number of calendar days before the manufacture or import of a substance exceeds a prescribed quantity, that a notifier must submit a New Substances Notification to Environment Canada (see also **assessment period**).

Polymer means a substance consisting of:

(a) molecules characterized by the sequence of one or more types of monomer units;

(b) a simple weight majority of molecules containing at least three monomer units that are covalently bound to at least one other monomer unit or reactant;

(c) less than a simple weight majority of molecules of the same molecular weight; and

(d) molecules distributed over a range of molecular weights wherein differences in the molecular weights are primarily attributable to differences in the number of monomer units (see also **monomer unit, reactant**).

Product development substance means a research and development substance that is evaluated in one program of two years or less in length before full commercialization by means of pilot plant trials, production trials, or customer trials to modify technical specifications in response to performance requirements of potential customers but does not include test marketing (see also **research and development substance, test marketing**).

Product of biotechnology means a substance manufactured using biotechnology. For the New Substances Notification Regulations, biotechnology products are microorganisms, parts of microorganisms, or substances produced by microorganisms (e.g. biochemicals and biopolymers), other organisms, or cell cultures.

Qualitative structure-activity relationship, sometimes referred to as a "read-across estimate", means a qualitative estimate of a property of a substance based on experimental data from other substance(s) having a closely related chemical structure (see also **read-across estimate, trivial structural difference**).

Reactant means, with respect to a polymer, a substance that is used intentionally in the manufacture of the polymer to become chemically part of the polymer composition (see also **polymer**).

Reactive functional group means an atom or associated group of atoms in a substance that is intended to, or can be reasonably anticipated to, undergo facile chemical reaction.

Read-across estimate means a qualitative estimate of a property of a substance based upon experimental data from another compound(s) having a closely related chemical structure (see also **qualitative structure-activity relationship, trivial structural difference**).

Regulations means the New Substances Notification Regulations of the *Canadian Environmental Protection Act*.

Research and development substance means a substance that is the subject of the systematic investigation or search, by means of experimentation or analysis, or both, that has as its primary objective the creation or improvement of a product or process including the determination of technical viability or performance characteristics, or both, but does not include test marketing (see also **product development substance, test marketing**).

Site-limited intermediate substance means a substance that is not a biotechnology product and that is manufactured or imported in a quantity that does not exceed an accumulated total of 50 000 kg and is:

(a) manufactured and consumed on the site of manufacture;

(b) involved in two sites by being manufactured at one site, transported to the second site, and consumed; or

(c) imported, transported directly to the site of consumption, and consumed such that the sum of the quantities of the substance referred to in paragraphs (a), (b), and (c) does not exceed 10 000 kg or for polymers does not exceed 20 000 kg at any one time (see also **consumed, intermediate substance**).

Substance. A substance is defined in subsection 3(1)of the CEPA, 1999 as:

> *"any distinguishable kind of organic and inorganic matter, whether animate or inanimate, and includes*

(a) *any matter that is capable of being dispersed in the environment or of being transformed in the environment into matter that is capable of being so dispersed or that is capable of causing such transformations in the environment;*

(b) *any element or free radical;*

(c) *any combination of elements of a particular molecular identity that originate in nature or are the result of chemical reactions but could not practicably be formed by simply combining individual constituents; and*

(d) *complex combinations of different molecules that originate in nature or are the result of chemical reactions but that could not practicably be formed by simply combining individual constituents."*

But, for the purposes of the new substances provisions of the CEPA, 1999 (section 66 and sections 80 to 89), does not include:

"(e) *any mixture that is a combination of substances and does not itself produce a substance that is different from the substances that were combined;*

(f) *any manufactured item formed into a specific physical shape or design during manufacture and has, for its final use, a function or functions dependent in whole or in part on its shape or design; and,*

(g) *any animate matter that is, or any complex mixture of different molecules that are, contained in effluents, emissions or wastes that result from any work, undertaking or activity."*

Substance occurring in nature means a substance that is naturally occurring, and is: unprocessed; processed only by manual, gravitational or mechanical means, by dissolution in water, by flotation, or by heating solely to remove water; or extracted from air by any means. These substances are considered to be on the DSL although they may not have been listed.

Test marketing means the exploration of market capability in a competitive situation where the creation or improvement of a product is not the primary objective (see also **product development substance, research and development substance**).

Transient reaction intermediate means a substance that is formed and consumed in the course of a chemical reaction.

Transitional period means the period between January 1, 1987 and June 30, 1994.

To which the person ought reasonably to have access means information in any of the offices of the company worldwide or other locations where the person can access the information (see also **in the person's possession**).

Trigger quantity means the quantity of substance imported or manufactured that, if exceeded, requires the notifier to provide a New Substances Notification. For example, for a non-transitional NDSL chemical, the trigger quantity requiring a Schedule I notification is 1 000 kg/yr or 5 000 kg accumulated, whichever is exceeded first.

Trivial structural difference means any structural variation of a substance that does not markedly alter, nor is reasonably expected to markedly alter physicochemical, biochemical, or toxicological properties.

UVCB is an acronym for **U**nknown or **V**ariable composition **C**omplex reaction products and **B**iological material. These materials are derived from natural sources or complex reactions and cannot be characterized in terms of constituent chemical compounds because their composition is too complex or variable. They are considered to be a single substance for notification purposes.

acute mammalian toxicity, 65, 78
additional information
  government request, 16, 104
  in person's possession, 72
  within reasonable access, 72
adsorption-desorption test, 63, 77
agent. *see* Canadian agent
algal acute toxicity, 67, 78
alloys, 19
amount manufactured or imported. *see* quantity
article. *see* item
assessment
  conclusions, 16, 103
  period, 100
assessment extension, notice of, 101
assessment period interruption, notice of, 101
biochemicals
  definition, 211
  determining information requirements, 31, 32, 33, 34, 35, 36, 37
  export only, 29, 35
  product development, 29, 34, 55, 71
  research and development, 29, 31
  site-limited, 36
  transitional, 32, 33, 34, 35, 36, 37
biodegradation. *see* ready biodegradability
biopolymer
  ultraviolet-visible spectrum, 192
biopolymers
  anionic, 67, 211
  cationic, 38, 67, 211
  concentrations of residual constituents, 64, 77
  decision schemes, 45, 46
  definition, 27, 211
  dispersibility in water, 64, 94
  export only, 45
  higher concern, 39
  hydrolysis, 64, 77, 192
  low-concern, 38
  naming, 59
  number-average molecular weight, 64
  polyesters, 39
  product development, 43, 45, 55, 71
  research and development, 45, 94
  residual constituents, 64, 77
  site-limited, 43, 45
  solubility in n-octanol, 65, 77, 191
  solubility in water, 64, 77, 191
  transitional, 45
  two percent rule, 24
  ultraviolet-visible spectrum, 65, 77
biotechnology, 27, 211
blends. *see* mixture
boiling point, 63, 77
bona fide intent to manufacture or import, 99
Canadian agent, 90, 91, 101
cell cultures, 27, 28
cement, 19
ceramic material, 19
certification statement, 90, 97
chemicals
  definition, 27, 212
  determining information requirements, 31, 34, 35, 36, 37
  export only, 29, 35
  naming, 59, 145
  product development, 29, 34, 55, 71
  research and development, 29, 31
  site-limited, 29, 36
  transitional, 32, 33, 34, 35, 36, 37, 48
compliance and enforcement, 17
Confidential Information Disclosure Regulations, 57, 98
confidential substances
  searching lists, 98
confidentiality requests, 92, 96
contaminants, 23
control measures, 103
corporate headquarters, 90
  request for confidentiality, 92
cryoscopy, 185
Daphnia acute toxicity, 66, 71, 78
data codes, 94
dispersibility in water, 64, 94
Domestic Substances List
  additions to, 104
  confidential entries, 99
  obtaining copies of, 57
ebulliometry, 184
effluents, material contained in, 22
EINECS inventory, 176
emergency measures information, 69
emissions, material contained in, 22
end-group analysis, 186
enforcement, 17
Enforcement and Compliance Policy, 17
enzymes
  two percent rule, 25
evidence that tissue was exposed, 66, 212
export only substances, 29, 35, 43, 45
fat solubility, 63, 77
fibre length distribution, 63
fire fighting information, 69
first aid information, 69
fish acute toxicity, 66, 71, 78
formulations. *see* mixture

frits, 19
gas chromatography, 189
gel permeation chromatography, 187, 188
glass, 19
GLP (Good Laboratory Practice), 93
Good Laboratory Practice (GLP), 74
higher concern polymers, 39
hotline. *see* New Substances Notification Information Line
human patch test, 65, 76
hydrates, 19, 158
hydrolysis, 63, 64, 77, 180, 192
import information, 68, 91, 92
  request for confidentiality, 93
impurities, 23
information sharing agreement, 73, 86, 93
intermediate. *see* transient reaction. *see* site-limited
item, 21, 30, 44
K_{ow}. *see* octanol-water partition coefficient
living organisms, 15
low quantity exclusion, 24
manufacture information, 67, 91, 92
  request for confidentiality, 93
masked names, 98, 194
Material Safety Data Sheet, 62, 94
melting point, 63, 77
microorganisms, 28, 62
mixture, 20
MSDS. *see* Material Safety Data Sheet
mutagenicity testing, 66, 74, 78, 82, 182
  Health Protection Branch Guidelines, 74, 82
  tissue exposure, 66, 212
naturally occurring substances, 20
New Substances Notification
  Information Line, 55
  Reference Number, 89, 95, 100
Non-domestic Substances List
  additions to, 47
  confidential entries, 47
  obtaining copies of, 57
  searching, 99
  substances on, 47
notice of excess quantity, 107
notification
  consultation, 88
  contents of test reports, 93
  exclusions, 20
  forms, 56
  language of text, 72, 89, 92
  mailing address, 89
  periods, 51
  product development substances, 55
  reporting experimental data, 93
  reporting research and development activity, 94
  supplying attachments, 94
notification rejection, notice of, 101
NSN form, 89
  how to obtain, 56
NSN Information Line, 55
number-average molecular weight, 64, 77, 184
octanol solubility, 65, 77, 191
octanol-water partition coefficient, 63, 65, 77, 191
OECD GLP, 74
  how to obtain, 81
OECD Test Guidelines, 74
osmometry, 185
particle size distribution, 63, 77
person
  interpretation of, 72
personal protective equipment information, 69
physical state, 94
PIN. *see* Product Identification Number
polyesters, 39
polymer
  ultraviolet-visible spectrum, 192
Polymers
  anionic, 67, 211
  cationic, 38, 67, 211
  concentrations of residual constituents, 64, 77
  decision schemes, 45, 46
  definition, 27, 214
  dispersibility in water, 64, 94
  export only, 43, 45
  higher concern, 39
  hydrolysis, 64, 77, 192
  low-concern, 38
  naming, 59
  number-average molecular weight, 64, 77, 184
  physical state, 94
  polyesters, 39
  product development, 43, 45, 55, 71
  ready biodegradability, 67, 78, 192
  research and development, 43, 45, 94
  residual constituents, 64, 77, 188
  site-limited, 43, 45
  solubility in n-octanol, 65, 77, 191
  solubility in water, 64, 77, 191
  transitional, 45, 46
  two percent rule, 24, 28
  ultraviolet-visible spectrum, 65, 77, 192
pre-polymer, 24, 59
product development, 29, 34, 43, 45, 55, 71
Product Identification Number, 69
products of biotechnology, 28, 142
proteins
  two percent rule, 25
QSAR. *see* quantitative structure-activity relationships

qualitative structure-activity relationships, 79
quality assurance, 74, 93
quality control, 74, 93
quantitative structure-activity relationships, 80
quantity manufactured/imported
  determining, 51
reaction product
  fully characterized, 21
  incidental, 24
read-across data, 79
ready biodegradability, 67, 78
repeated dose mammalian toxicity, 66, 78
  routes of exposure, 65
requesting confidentiality, 92
research and development, 29, 31, 43, 45, 94
routes of exposure, 65, 213
Section 70 of the CEPA, 1999, 94, 95, 108
Significant New Activity. *see* SNAc Notice
site-limited intermediates, 29, 36, 43, 45
skin irritation, 65, 76, 78, 182
skin sensitization, 65, 76, 78, 182
SNAc Notice, 20
spectroscopy, 64, 190, 192
steel, 19
substance
  carried through Canada, 24
  condition on manufacture or import, 16, 103
  confidential, 47, 93, 98
  masked name, 98, 194
  naming, 59
  naturally occuring, 20
  notifiable transitional, 25
  prohibition of manufacture or import, 16, 103
  reference, 74, 93
  regulated by other Acts, 22
  requesting additional information, 16, 104
successor corporation, 72
supercritical fluid chromatography, 190
suspicion of toxicity, 103
technical contact, 73, 91
test marketing, 29, 43, 214, 215
  definition, 216
test methods
  alternative, 75
  recommended, 74, 184
  sources, 81
toll manufacture, 29, 43
toxic
  definition, 102
  suspicion of, 103
transient reaction intermediates, 23
transitional period, 25, 48
transitional substance, 25, 32, 33, 34, 35, 36, 37, 45, 46, 48
  five-year post transitional period, 46
transport information, 69
trigger quantities
  biochemicals, 31, 32, 33, 34, 35, 36, 37
  biopolymers, 45, 46
  chemicals, 31, 32, 33, 34, 35, 36, 37
  polymers, 45, 46
trivial structural difference, 79
TSCA inventory, 47, 175
ultraviolet-visible spectrum, 65, 77, 192
UVCB
  naming, 59, 173
  testing, 81
vapour pressure, 63, 77
waivers
  based on data impractical to obtain, 87
  based on information unnecessary for assessment, 85
  based on limited use or exposure, 85
  publication of, 84
  request of, 84
waste, material contained in, 22
water solubility, 64, 77, 191